



4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 438, 440, and 460

Office of the Secretary

45 CFR Parts 86, 92, 147, 155, and 156

Docket No.: HHS-OCR-2019-0007

RIN 0945-AA11

Nondiscrimination in Health and Health Education Programs or Activities

AGENCY: Centers for Medicare and Medicaid; Office for Civil Rights (OCR), Office of the Secretary, HHS

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services (“the Department”) is committed to ensuring the civil rights of all individuals who access or seek to access health programs or activities of covered entities under Section 1557 of the Patient Protection and Affordable Care Act. The Department proposes to revise its Section 1557 regulation in order to better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.

DATES: Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments to this proposed rule, identified by RIN 0945-AA11, by any of the following methods:

- *Federal eRulemaking Portal.* You may submit electronic comments at <http://www.regulations.gov> by searching for the Docket ID number HHS-OCR-2019-0007. Follow the instructions at <http://www.regulations.gov> online for submitting comments through this method.

- *Regular, Express, or Overnight Mail:* You may mail comments to U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Section 1557 NPRM, RIN 0945-AA11, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW, Washington, DC 20201.

- *Hand Delivery / Courier:* You may hand deliver comments to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Section 1557 NPRM, RIN 0945-AA11, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW, Washington, DC 20201.

All comments received by the methods and due date specified above will be posted without change to <http://www.regulations.gov>, including any personal information provided, and such posting may occur before or after the closing of the comment period.

We will consider all comments received by the date and time specified in the “DATES” section above, but, because of the large number of public comments we normally receive on *Federal Register* documents, we are not able to provide individual acknowledgements of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays. Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the lobby of the building. Electronic comments with attachments should be in Microsoft Word or Excel; however, we prefer Microsoft Word.

Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For complete access to background documents or posted comments, go to <http://www.regulations.gov> and search for Docket ID number HHS-OCR-2019-0007.

FOR FURTHER INFORMATION CONTACT: Luben Montoya, Supervisory Civil Rights Analyst, HHS Office for Civil Rights at (800) 368-1019 or (800) 537-7697 (TDD).

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I. Executive Summary

A. Background on Section 1557 and Its Rulemaking

Section 1557 of the Patient Protection and Affordable Care Act (“PPACA”)¹ prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity that receives Federal financial assistance, or under any program or activity that is administered by an executive agency under Title I of the PPACA or by an entity established under such Title. Section 1557 cites Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (“Title VI”), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (“Title IX”), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) (“Age Act”),

¹ Patient Protection and Affordable Care Act, Pub. L. 111-148, sec. 1557, 124 Stat. 119, 260 (Mar. 23, 2010) (codified at 42 U.S.C. 18116). In this Notice of Proposed Rulemaking, we refer interchangeably to Section 1557 and 42 U.S.C. 18116.

and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (“Section 504”).² It further states that “[t]he enforcement mechanisms provided for and available” under those laws “shall apply for purposes of violations” of Section 1557.³

Section 1557 authorizes, but does not require, the Secretary of Health and Human Services (“Secretary”) to promulgate regulations implementing Section 1557’s nondiscrimination requirements.⁴

On August 1, 2013, the Department issued a Request for Information (RFI) soliciting input on regulations under Section 1557. 78 FR 46558. Thereafter, on September 8, 2015, the Department issued a Notice of Proposed Rulemaking (NPRM) to add a new part 92 to Title 45 of the Code of Federal Regulations and thereby impose numerous new requirements on covered entities.⁵ 80 FR 54172.

On May 18, 2016, the Department finalized its proposed regulations for Section 1557 in 45 CFR Part 92 (the “Final Rule,” “current rule,” or the “Section 1557 Regulation”). 81 FR 31376.⁶ As noted above, Section 1557 bars discrimination on grounds prohibited under several civil rights statutes, including on the ground of sex under Title IX of the Education Amendments of 1972. In its Section 1557 Regulation, the Department defined discrimination “on the basis of sex” to cover,

² While Section 1557 does not incorporate nondiscrimination provisions by reference to Title VII, it provides that nothing in Title I of the PPACA is to be construed as invalidating or limiting the rights, remedies, procedures, or legal standards available under certain civil rights laws, and mentions Title VII specifically. 42 U.S.C. 18116(b).

³ 42 U.S.C. 18116(a).

⁴ 42 U.S.C. 18116(c).

⁵ See 45 CFR 92.4 (“Covered entity means: (1) An entity that operates a health program or activity, any part of which receives Federal financial assistance; (2) An entity established under Title I of the PPACA that administers a health program or activity; and (3) The Department.”).

⁶ The Final Rule was later revised on July 18, 2016, when the Department issued a technical correction deleting an incorrect toll-free telephone number to call the Department to file a civil rights complaint. 81 FR 46613 (July 18, 2016).

among other things, discrimination on the basis of sex stereotyping, gender identity, and termination of pregnancy, but explicitly declined to include discrimination on the basis of sexual orientation. 81 FR 31390 (“OCR has decided not to resolve in this rule whether discrimination on the basis of an individual’s sexual orientation status alone is a form of sex discrimination.”). As explained more fully below, the Final Rule, among other things, imposed specific requirements regarding language assistance services, multi-language “taglines,” and nondiscrimination notices.

The Department estimated that, collectively, the Final Rule’s new requirements, backed by the threat of enforcement action, would cost health care providers and other covered entities over \$942.5 million in the first five years of implementation. 81 FR 31459.

The Final Rule became effective on July 18, 2016, except to the extent that the Rule required changes to health insurance or group health plan benefits or benefit design, in which case the Final Rule applied on the first day of the first plan year that began on or after January 1, 2017. 45 CFR 92.1.

On January 20, 2017, the President issued E.O. 13765 “Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal,” that requires, among other things, “[t]o the maximum extent permitted by law, the Secretary of Health and Human Services . . . shall exercise all authority and discretion available to [] waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [PPACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of

healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” 82 FR 8351 (Jan. 24, 2017).

B. Litigation Challenging the Section 1557 Regulation

Lawsuits challenging the regulations followed promulgation of the Final Rule. On August 23, 2016, the States of Texas, Wisconsin, Nebraska, Kentucky, and Kansas, along with three private health care providers, filed a complaint in the U.S. District Court for the Northern District of Texas challenging the Section 1557 Regulation. See *Franciscan Alliance, Inc., et al. v. Burwell, et al.*, 227 F. Supp. 3d 660 (N.D. Tex. 2016). The complaint stated that, “by redefining a single word used in the Affordable Care Act ... HHS has created a massive new liability for thousands of healthcare professionals unless they cast aside their medical judgment and perform controversial and even harmful medical transition procedures.” Complaint, *Franciscan Alliance, Inc., et al. v. Burwell, et al.*, No. 7:16-cv-00108-O (N.D. Tex. Aug. 23, 2016). Two other cases with similar objections were filed in the U.S. District Court for the District of North Dakota. *Religious Sisters of Mercy, et al. v. Burwell, et al.*, No. 3:16-cv-386 (D.N.D. filed Nov. 7, 2016); *Catholic Benefits Association, et al. v. Burwell, et al.*, No. 3:16-cv-432 (D.N.D. filed Dec. 28, 2016).⁷

On December 31, 2016, the U.S. District Court in *Franciscan Alliance* issued a nationwide preliminary injunction against the Department, barring it from enforcing the Section 1557 Regulation’s prohibition against discrimination on the basis of “gender identity” and “termination of pregnancy.” 227 F. Supp. 3d at 696.

⁷ *Religious Sisters of Mercy, et al. v. Burwell, et al.*, No. 3:16-cv-386; *Catholic Benefits Association et al., v. Burwell, et al.*, No. 3:16-cv-432 (D.N.D. order of Jan. 23, 2017, consolidating North Dakota cases).

The district court held that the Department had adopted an erroneous interpretation of “sex” under Title IX, and that the regulation was also arbitrary and capricious for failing to incorporate Title IX’s religious and abortion exemptions. *Id.* The district court concluded that the Department’s interpretation was not entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), because “the meaning of sex in Title IX unambiguously refers to the biological and anatomical differences between male and female students as determined at their birth.” 227 F. Supp. 3d at 687 (citations omitted).

The *Franciscan Alliance* district court also held that plaintiffs had established a likelihood of success on the merits of their claims that the Department had violated the Administrative Procedure Act (APA) and the Religious Freedom Restoration Act (RFRA). *Id.* at 693. Regarding the RFRA claim, the district court found that HHS had not demonstrated a compelling interest in enforcing the regulation against the plaintiffs. *Id.* at 696. And even if the Department had demonstrated that compelling interest, the court held that the Department failed to show that its interest could not be pursued through less restrictive means for providing access to, and coverage for, services related to gender dysphoria. *Id.* at 693. The U.S. District Court for the District of North Dakota found the *Franciscan Alliance* order to be “thorough and well-reasoned,” and on that basis temporarily stayed enforcement of Section 1557’s prohibitions against discrimination on the

bases of gender identity and termination of pregnancy against the named plaintiffs in that court's two consolidated cases.⁸

On July 10, 2017, the *Franciscan Alliance* court stayed proceedings to allow time for agency reconsideration, finding that the preliminary injunction order “provides sufficient guidance for HHS’s review of the Rule.”⁹ The U.S. District Court for the District of North Dakota also further stayed the proceedings in its two cases on July 10, 2017 and on August 24, 2017.¹⁰ Neither the previous Administration nor the current one appealed the nationwide preliminary injunction, or the orders in *Franciscan Alliance*, *Religious Sisters of Mercy*, or *Catholic Benefits Association*, staying proceedings. On May 2, 2017, the Department of Justice (DOJ) moved the Northern District of Texas for a voluntary remand and stay to allow HHS to “reassess the reasonableness, necessity, and efficacy of the two aspects of the [Section 1557] regulation that are challenged” in litigation.¹¹ DOJ filed a similar motion with the District of North Dakota later that month.¹²

On July 10, 2017, the *Franciscan Alliance* court stayed proceedings to allow time for agency reconsideration, finding that the court’s preliminary injunction order “provides sufficient guidance for HHS’s review of the Rule.”¹³ The district

⁸ *Religious Sisters of Mercy, et al. v. Burwell, et al.*, Nos. 3:16-cv-386 & 3:16-cv-432 (D.N.D. Order of January 23, 2017).

⁹ *Franciscan Alliance*, No. 7:16-cv-00108-O (filed July 10, 2017).

¹⁰ *Religious Sisters of Mercy, et al. v. North Dakota v. Burwell, et al.*, No. 3:16-cv-386 (D.N.D. Order filed on July 10, 2017; *Catholic Benefits Association v. Burwell*, No. 3:16-cv-432 (D.N.D. Order filed Aug. 24, 2017).

¹¹ See Defendant’s Motion, *Franciscan Alliance*, No. 7:16-cv-00108-O (filed May 2, 2017).

¹² Defendant’s Motion, *Religious Sisters of Mercy*, No. 3:16-cv-386 (filed May 26, 2017).

¹³ *Franciscan Alliance*, No. 7:16-cv-00108-O (filed July 10, 2017).

court in North Dakota similarly stayed proceedings on August 24, 2017, in order to allow HHS “to reconsider the controversial rules and regulations at issue.”¹⁴

On February 4, 2019, the plaintiffs in the *Franciscan Alliance* case filed briefs in support of their renewed motions for summary judgment. On April 5, 2019, DOJ filed a brief in response to plaintiffs’ motion summary judgment on behalf of HHS,¹⁵ stating that “the relevant provisions of Title IX and Section 1557 unambiguously exclude gender-identity discrimination.” *Id.* at 14. In this brief, DOJ stated the position of the U.S. Government on the meaning of “sex” under Title VII of the Civil Rights Act, Title IX of the Education Amendments of 1972, and Section 1557 of PPACA. DOJ stated, “Since the [Section 1557 Final] Rule was issued, the United States has returned to its longstanding position that the term ‘sex’ in Title VII does not refer to gender identity, and there is no reason why Section 1557, which incorporates Title IX’s analogous prohibition on ‘sex’ discrimination, should be treated differently.” *Id.* at 6. Therefore, DOJ concluded, “the [Final] Rule’s prohibitions on discrimination on the basis of gender identity and termination of pregnancy conflict with Section 1557 and thus are substantively unlawful under the APA.” *Id.* DOJ continued, “[t]he [Final] Rule also fails to incorporate Title IX’s exemptions despite Section 1557’s directive to the contrary, thereby prohibiting conduct the statute permits.” *Id.*

¹⁴ *Religious Sisters of Mercy*, No. 3:16-cv-432 (order of Aug. 24, 2017).

¹⁵ See Defendant’s Memorandum in Response to Plaintiffs’ Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-0 (filed April 5, 2019).

While it reconsiders its Section 1557 Regulation through the rulemaking process, the Department continues to abide by the preliminary injunction, which remains in place.

C. Summary of the Proposed Rule

In order to better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557, the Department proposes to make substantial revisions to the Section 1557 Regulation and to eliminate provisions that are inconsistent or redundant with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability. In addition, to resolve confusion raised by the Section 1557 Regulation's reliance on an outdated version of the Department's Title IX regulation, the Department proposes to amend its Title IX regulation to implement statutory amendments made by Congress to Title IX in 1988.¹⁶

The proposed rule would retain the obligation imposed on covered entities to submit assurances of compliance, certain provisions concerning language access for individuals with limited English proficiency (LEP), and certain provisions ensuring access for individuals with disabilities. The proposed rule would empower the Department to continue its robust enforcement of civil rights laws prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability in

¹⁶ See Civil Rights Restoration Act of 1987, Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (amending Title IX). These proposed changes would better align HHS's regulations to the Title IX regulations adopted by other agencies and the position of the Department of Justice, the Federal civil rights coordinating authority under Executive Order 12250. See Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws, 45 FR 72995 (Nov. 2, 1980).

Department-funded health programs or activities, and would make it clear that such civil rights laws remain in full force and effect.

The Department further proposes to make limited conforming amendments to ten provisions in relevant Department regulations.

D. Cost-Effective Design of the Proposed Rule

The proposed rule would be an economically significant deregulatory action. The Department projects that the proposed rule would result in approximately \$3.6 billion in cost savings (undiscounted) over the first five years after finalization. The Department anticipates that the largest proportion of these estimated savings would result from repealing the Section 1557 Regulation's provisions related to mandatory notices. Specifically, the proposed rule would repeal requirements on covered entities to mail beneficiaries, enrollees, and others, notices concerning non-discrimination and the availability of language assistance services (in 15 languages) with every "significant" publication and communication larger than a postcard or brochure. The Department projects additional savings from eliminating the requirement for OCR to weigh the presence or absence of language access plans, and from repealing provisions that duplicate disability and sex discrimination regulatory requirements concerning covered entities establishing grievance procedures. The Department estimates that there will be some additional costs to covered entities regarding training and revision of policies and procedures if the proposed regulation is finalized.

The Department believes that the anticipated benefits—which include compliance with Federal law, appropriate respect for the roles of Federal courts and

Congress, and reduction or elimination of ineffective, unnecessary, or confusing provisions—far outweigh any costs or burdens that may arise from the proposed changes.

II. Reasons for the Proposed Rulemaking

Section 1557 does not require any implementing regulations, but incorporates and builds on the existing civil rights framework of Title VI, Title IX, Age Act, and Section 504 by making the nondiscrimination requirements of such laws applicable to certain health programs or activities and related entities to the extent they do not already apply to such programs or activities. With this background in mind, the Department has decided to substantially revise the Section 1557 Regulation for several reasons.

The Department believes that the Final Rule exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs. As stated in the *Franciscan Alliance* litigation, “the Rule’s prohibitions of discrimination on the basis of gender identity and, without the accompanying statutory protections, termination of pregnancy are substantively unlawful under the APA.”¹⁷ The existence of lawsuits and court orders blocking enforcement of significant parts of the Final Rule for over two years indicates that changes in the proposed rule may minimize litigation risk.

¹⁷ See Defendant’s Memorandum in Response to Plaintiffs’ Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-0 at *5 (filed April 5, 2019).

For all these reasons, the Department proposes to exercise its discretionary regulatory authority to revise the Section 1557 Regulation to implement Federal civil rights law consistent with the applicable statutes as passed by Congress. The Department believes these amendments would reduce the significant confusion and unjustified burdens caused by the Final Rule.

First, the Final Rule created inconsistencies with, and unnecessarily duplicated, the Department's long-standing existing civil rights regulations. *See* 45 CFR Parts 80 and 81 (Title VI), 84 and 85 (Section 504), 86 (Title IX), 90 and 91 (Age Act). Therefore, the Department proposes to repeal the provisions of the Final Rule that are confusing and redundant.

Second, the U.S. District Court for the Northern District of Texas preliminarily enjoined enforcement of parts of the Section 1557 Regulation because it found that the Department had exceeded its statutory authority.¹⁸ The Department proposes this rule to address the overbroad interpretations, adopted in the current rule, of Section 1557 that were identified by the court and other Federal precedents. The Department also proposes to address the court's findings by incorporating, into the Department's implementing regulations, certain amendments to the statutes expressly identified by Congress in Section 1557.

Third, the Department estimates that the prior rulemaking did not anticipate or account for an annual burden of approximately \$147 million (low-end) to \$1.34 billion dollars (high-end), as further described in the Regulatory Impact Analysis of this proposed rule. The Department does not believe those burdens are justified by

¹⁸ *See Franciscan Alliance*, 227 F. Supp. 3d at 696.

need, or by the benefits obtained by the rulemaking. In total, the proposed rule would relieve the American people of approximately \$3.6 billion in unjustified costs over five years, while continuing to provide for vigorous enforcement of civil rights protections in health care. *See* Executive Order 13765, 82 FR 8351 (Jan. 20, 2017) (“Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal”).

As discussed below, the Department believes the repeal and replacement of significant portions of the Section 1557 Regulation would provide much needed finality, predictability, administrability, consistency, relief of burdens, and clarity, all of which would benefit covered entities, beneficiaries of Exchanges, and Department-funded or administered health programs or activities, the courts, and the general public.

In light of these determinations, through this proposed rule, the Department proposes to codify the longstanding application of the civil rights laws cited in Section 1557 to health programs or activities receiving Federal financial assistance or programs or activities administered by the Department under Title I of the PPACA or by entities established under such Title, both in terms of the protections those civil rights laws provide and the enforcement mechanisms they entail. This approach faithfully implements the Congressional mandate and seeks to avoid further litigation and uncertainty regarding the implementing regulations. The Department seeks comment on all of the provisions that are retained under this proposed rule, or that this rule proposes to repeal, amend, or add, including comment on whether provisions of the current Section 1557 Regulation that the

Department does not propose to retain in this proposed rule, if any, are in keeping with Congress’s mandate such that the Department should consider retaining them – and whether any of such provisions should be incorporated into the Department’s regulations implementing the underlying civil rights laws.

A. Section 1557 of the PPACA Does Not Prevent or Limit Reconsideration of the Current Rule.

Section 1557(c) states that the Secretary “may” promulgate implementing regulations. This language contrasts with the multiple other areas of Title I of the PPACA where Congress directed that the Secretary (or Secretaries) “shall” issue regulations. 42 U.S.C. 18116(c). Section 1557 accordingly authorizes, but does not require, the Secretary to implement the statute through regulation. That approach makes sense because “Section 1557 builds on a landscape of existing civil rights laws.” 78 FR 46559 (RFI) (Aug. 1, 2013). Section 1557 vests the Department with discretion to determine whether and to what degree implementing regulations are needed, and to revisit that determination, as appropriate, at a later date. *Encino Motorcars v. Navarro*, 146 S.Ct. 2117, 2125 (2016) (“Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change”). (*ConocoPhillips Co. v. U.S. E.P.A.*, 612 F.3d 822, 832 (5th Cir. 2010) (“[e]mbedded in an agency’s power to make a decision is its power to reconsider that decision.”); *New England Power Generators Assn. v. FERC*, 879 F.3d 1192 (D.C. Cir. 2018) (“So long as any change is reasonably explained, it is not arbitrary and capricious for an agency to change its mind in light of experience, or in the face of new or additional evidence, or further analysis or other factors indicating that the

agency’s earlier decision should be altered or abandoned.”). Thus, an agency action to substantially repeal a prior rule, or parts thereof, is not necessarily subject to a higher standard of justification in the exercise of such discretion compared to the level of justification required under the prior rulemaking on a blank slate. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (“When an agency changes its existing position, it need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate. But the agency must at least display awareness that it is changing position and show that there are good reasons for the new policy.”). The agency’s use of its rulemaking discretion in revisiting its original position is not, therefore, subject to a higher standard under the APA (5 U.S.C. 706); otherwise, agencies would be limited in their ability to revisit past regulations to cure defects or provide clarifications.

B. The Final Rule Adopted Novel and Inconsistent Legal Interpretations of Long-Standing Civil Rights Law.

1. The Final Rule Interpreted the Scope of Section 1557 Too Broadly.

The Department has now concluded that its existing Section 1557 Regulation impermissibly extends to programs and entities not covered by the text of the statute. With respect to the receipt of Federal financial assistance, the current rule defines “health program or activity” to cover “all [] operations” of entities principally engaged in providing or administering “health services or health insurance coverage or other health coverage.” 45 CFR 92.4. The scope of the regulation then includes all the operations of entities that provide “health insurance coverage or other health coverage,” whether or not they provide any health care.

The Civil Rights Restoration Act of 1987 (CRRA), however, defined “program or activity” for purposes of Title VI, Section 504 of the Rehabilitation Act, the Age Act, and Title IX to cover all operations of regulated entities only when they are “*principally engaged* in the business of providing education, health care, housing, social services, or parks and recreation.” Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (emphasis added). The “business of providing . . . health care” differs substantially from the business of providing health insurance coverage (or other health coverage) for such health care. Thus, the Final Rule goes beyond the CRRA by covering all the operations of entities that provide “health insurance coverage or other health coverage” and extends to those that are not principally engaged in the business of providing health care, and to those who provide no health care at all.¹⁹ Moreover, the Department had not previously interpreted the CRRA to cover all the operations of health insurance providers under any of the antidiscrimination laws covered by the CRRA (Title VI, Title IX, the Age Act, and Section 504) until it promulgated the Section 1557 regulation – over a quarter century after the CRRA was passed – despite there being nothing in Section 1557 indicating any abrogation – or expansion – of the CRRA. Therefore, the Department is now proposing to clarify that health insurance programs administered by entities not principally engaged in providing health care will only be covered by the Rule to the extent those programs (as opposed those entities) receive Federal financial assistance from the Department.

¹⁹ The preamble to the Final Rule acknowledges the relevance of the CRRA, 81 FR at 31386, but does not explain how the provision of “health care” covers the provision of “health insurance, even if only part of the health program or activity receives such assistance.”

2. The Final Rule Improperly Blended Substantive Requirements and Enforcement Mechanisms of the Underlying Statutes.

The PPACA states that the “enforcement mechanisms for and available under [] title VI, title IX, section 504, or such Age Discrimination Act shall apply,” for purposes of enforcing Section 1557. 42 U.S.C. 18116(a). Interpreting this provision in 2015, a Federal court held “Congress’s express incorporation of the enforcement mechanisms from those four Federal civil rights statutes, as well as its decision to define the protected classes by reference thereto, manifests an intent to import the various *different* standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.” *Southeastern Pennsylvania v. Gilead*, 102 F. Supp. 3d 688, 698-99 (E.D. Pa. 2015) (emphasis added). *See also Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) (“If Congress intended for a single standard to apply to all § 1557 discrimination claims, repeating the references to the civil-rights statutes and expressly incorporating their distinct enforcement mechanisms would have been a pointless (and confusing) exercise.”).

In interpreting and enforcing Section 1557 prior to the promulgation of the Final Rule – *i.e.*, from 2010 to 2016 – the Department applied Title VI, Title IX, Section 504, and the Age Act regulations as independent authorities. However, contrary to the text of Section 1557, the Final Rule did not merely take existing protected classes and enforcement mechanism and apply them to health care programs or activities. Rather, it made certain individualized requirements, prohibitions, or enforcement mechanisms apply across all protected classes without sufficient statutory or regulatory support. This hodgepodge approach at times

resulted in conflicts with precedents of the U.S. Supreme Court and lower Federal courts. *See* 81 FR 31387 (stating in the preamble of the Final Rule that there is “ a cognizable national origin discrimination claim under Title VI, Section 1557, and this part when the claim alleges that a covered entity’s use of a facially neutral policy or practice related to citizenship or immigration status has a disparate impact on individuals of a particular national origin group”); *see also* 81 FR at 31440 (“OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation”); 81 FR 31405 (“OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly”). *But see Alexander v. Sandoval*, 532 U.S. 275, 282 (2001) (denying private rights of action for disparate impact theories under Title VI).

The Final Rule stated that an individual or entity may bring a civil action to challenge a violation of Section 1557 or of the regulation in Federal court. 45 CFR 92.302(d). The Department explained in the preamble to the Final Rule that private rights of action were available for Section 1557 claims against recipients of Federal financial assistance or State Exchanges for racial, national origin, sex, age, or disability discrimination. *See* 81 FR at 31440 (stating that “both the proposed and the final rule specify that a private right of action is available under Section 1557” and such actions are available “on the basis of any of the criteria enumerated in the legislation”). Multiple Federal courts have held that Section 1557, or the statutes

underlying it, do not permit private rights of action for disparate impact claims of discrimination on the basis of race²⁰ or sex,²¹ and there is a split on the question with respect to disability, with one Federal appellate court holding that such private rights of action are not available and other Federal appellate courts holding that such private rights of action are available for claims of discrimination on the basis of disability.²²

These judicial interpretations of Section 1557 relied on Congress's decision to include a rule of construction in Title IX stating that it does not require educational institutions to use preferential treatment based on a disparate impact basis,²³ and the U.S. Supreme Court's decisions precluding a right of action for disparate impact claims under Title VI.²⁴

The Final Rule also stated that compensatory damages are available in appropriate administrative and judicial actions under the Section 1557 Regulation,

²⁰ See *Southeastern Pennsylvania Transp. Authority v. Gilead*, 102 F. Supp. 3d 688, 698-701 (E.D. Pa. 2015) (holding that Section 1557, incorporating Title VI, does not permit a private right of action for a disparate impact claim on the basis of race); see also *Alexander v. Sandoval*, 532 U.S. 275, 282-83 (2001).

²¹ See *Condry v. UnitedHealth Group*, No. 17-cf-00183-VC (N.D. Calif. 2018) ("disparate impact claims on the basis of sex are not cognizable under section 1557"); *Weinreb v. Xerox Business Services*, 323 F. Supp. 3d 501, 521 (S.D.N.Y. 2018); *Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017); *York v. Wellmark, Inc.*, No. 4:16-cv-00627-RGE-CFB, at *15-16 (S.D. Iowa Sep. 6, 2017); *Southeastern Pennsylvania v. Gilead*, 102 F. Supp. 3d 688 (E.D. Pa. 2015).

²² Compare *Crocker v. Runyon*, 207 F.3d 314, 321 (6th Cir. 2000); *Doe v. Bluecross Blueshield*, No. 2:17-cv-02793-TLP-cgc, 2018 WL 3625012 (W.D. Tenn. 2018); and *Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017), with *Valencia v. City of Springfield, Ill.*, 883 F.3d 959, 967 (7th Cir. 2018); and *Hollenbeck v. U.S. Olympic Comm.* 513 F.3d 1191, 1197 (10th Cir. 2008). To the Department's knowledge, no disparate impact claims on the basis of age have been filed under Section 1557 in a Federal court.

²³ 20 U.S.C. 1681(b) (Title IX "[s]hall not [be] construe[d] to require an educational institution to grant preferential or disparate treatment to the members of one sex on account of an imbalance which may exist with respect to the total number or percentage of persons of that sex participating in or receiving the benefits of any Federally supported program or activity, in comparison with the total number or percentage of persons of that sex in any community, State, section, or other area.").

²⁴ *Alexander v. Sandoval*, 532 U.S. 275, 282 (2001) (holding that private rights of action for disparate impact are not authorized by Title VI).

45 CFR 92.301(b), and the Department stated in its preamble that this was added “to make clear in the regulation that compensatory damages are available. Our interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX,” 81 FR at 31440. However, the Department of Justice’s Title VI Manual states that, under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on an agency’s disparate impact regulations.²⁵

The Final Rule also newly extended provisions applicable only to some of the underlying civil rights laws to apply to all of the prohibited bases of discrimination under Section 1557. For example, although only the Section 504 (disability) and Title IX (sex) regulations prohibit recipients from perpetuating discrimination by providing significant assistance to any agency, organization, or person that discriminates, the Final Rule extended this prohibition to Title VI and Age Act claims under Section 1557.²⁶ The Section 1557 Regulation similarly extended the prohibition, in the Title VI, Section 504, and Age Discrimination Act regulations, on the utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination, to claims of discrimination on the basis of

²⁵ DOJ Title VI manual, <https://www.justice.gov/crt/fcs/T6Manual9> (citing *Alexander v. Sandoval*, 532 U.S. 275, 282-83 (2001), *Barnes v. Gorman*, 536 U.S. 181, 187 (2002), and *Gebser v. Lago Vista Indep. Sch.*, 524 U.S. 274, 87 (1998)).

²⁶ See 45 CFR 84.4(b)(1)(v) (Section 504), 86.23(b)(7) (Title IX). *But see* 45 CFR 92.101(a)(4)(ii) (extended to age under Section 1557 Regulation), § 92.101(b)(1)(ii) (extended to race, color or national origin under Section 1557 Regulation).

sex under Section 1557, although that prohibition is not included in the Title IX regulations.²⁷

3. HHS Interpreted Federal Nondiscrimination Law Differently From Other Federal Agencies.

Because Section 1557, Title VI, Title IX, Section 504, and the Age Act are cross-cutting civil rights laws enforced by multiple Federal agencies the Department's interpretation of these laws should be consistent with other interpretations within the Executive Branch.²⁸ By applying different substantive requirements and enforcement mechanisms, as discussed above, HHS's Final Rule differed from other agencies' regulations on Title VI, Title IX, Section 504, and the Age Act. HHS's Section 1557 Regulation is limited in scope to HHS-funded or HHS-administered health programs, activities, and PPACA Title I entities, but Section 1557 of the PPACA applies to health programs or activities which receive Federal financial assistance from any Executive agency.²⁹ Although the then-OCR Director

²⁷ See 45 CFR 80.3(b)(2) (Title VI), 84.4(b)(4) (Section 504), 91.11(b) (Age Act). *But see* 45 CFR 92.101(b)(3)(ii) (extended to sex under Section 1557 Regulation).

²⁸ Pursuant to Executive Order 12250, the Attorney General has the responsibility to "coordinate the implementation and enforcement by Executive agencies of (a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), (b) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), (d) Any 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." Executive Order 12250 at sec. 1-2(b), 45 FR 72995 (Nov. 2, 1980). *See also* 42 U.S.C. 6103 (requiring each Federal department or agency to submit Age Act enforcement reports to and obtain approval of their Age Act regulations by HHS).

²⁹ Compare 42 U.S.C. 18116(a) (stating that Section 1557 applies to "any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by *an Executive Agency* or any entity established under this title (or amendments)") (emphasis added) with 45 CFR 92.1 (stating that Part 92 applies to health programs or activities administered by recipients of Federal financial assistance from the *Department*, Title I entities that administer health programs or activities, and *Department-administered* health programs or activities) (emphasis added).

encouraged other agencies to adopt the standards in the Final Rule in 2016,³⁰ each agency has its own enforcement responsibility for the programs they fund that fall within Section 1557 jurisdiction. One agency's implementation and enforcement of a civil rights law that is inconsistent with other agencies would result in confusion for entities regulated by more than one agency and for the public as a whole, which is particularly imprudent given that Federal courts have implied the availability of monetary damages in private rights of action under the underlying civil rights statutes.³¹

4. The Final Rule Created New Provisions Concerning Language Access Not Adequately Justified by Law or Policy.

Title VI prohibits discrimination against persons on the basis of national origin under any program or activity receiving Federal financial assistance. Under governing U.S. Supreme Court case law, Title VI obligates recipients of Federal financial assistance to provide individuals with limited English proficiency (LEP) meaningful access to Federally funded programs or activities.³² In 2016, the Section 1557 Final Rule added certain language access provisions that were not required by Title VI case law or the underlying Title VI regulation.³³

³⁰ Memorandum from OCR Director to Civil Rights Heads of Federal Agencies, Enforcement Responsibilities under Section 1557 of the Affordable Care Act (July 12, 2016), <https://www.hhs.gov/sites/default/files/directors-memo-july2016.pdf>.

³¹ *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 272 (3d Cir. 2014) (Title VI); *Franklin v. Gwinnett Cty. Pub. Sch.*, 503 U.S. 60 (1992) (Title IX).

³² *Lau v. Nichols*, 414 U.S. 563 (1974) (interpreting Title VI in the Department of Health Education and Welfare's Title VI regulation). The Title VI statute does not expressly mention "limited English proficiency." 42 U.S.C. 2000d *et seq.* *Lau* and its progeny relied on the word "national origin" in Title VI to encompass limited English proficiency (LEP).

³³ See 45 CFR Parts 80 and 81 (the Department's Title VI regulations do not expressly reference LEP). *Lau* and subsequent case law interpreted the Title VI regulations' prohibition on recipients of Federal financial assistance "utiliz[ing] criteria or methods of administration which have the effect of

Additionally, the Final Rule introduced confusing and costly notice and tagline requirements that were not required by law, were inconsistent with tagline requirements required by other components of the Department and, as discussed further below, provided relatively minimal benefit to LEP individuals. Complicating matters further, because the Section 1557 Regulation applies only to health care programs or activities, a recipient of Federal financial assistance from the Department for health care services is subject to different notice and tagline requirements than a recipient receiving Federal financial assistance from the Department for human services alone, such as a child welfare agency.

Furthermore, the Final Rule newly required the OCR Director, in evaluating compliance, to take into account whether a recipient of Federal financial assistance has “developed and implemented an effective written language access plan that is appropriate to its particular circumstances, to be prepared to meet its obligations” under Section 1557. 45 CFR 92.201(b)(2). Before the promulgation of the Final Rule, an Executive Order directed Executive *agencies* to prepare language access plans applicable to their Federally conducted programs and activities (for example, the Veterans Administration’s hospitals), but the Section 1557 provision applied to *recipients* of Federal financial assistance (for example, private hospitals accepting Medicaid). E.O. 13166, sec. 2, 65 FR 50121, 50121 (Aug. 16, 2000). The last section

subjecting individuals to discrimination” on the basis of national origin to require recipients to take reasonable steps to provide persons with limited English proficiency (LEP) meaningful access to Federally funded programs or activities. The Supreme Court has not specified what particular linguistic requirements may constitute “meaningful access” outside of the education context.

of the Executive Order also stated that it “does not create any right or benefit, substantive or procedural, enforceable at law.” 65 FR 50122.

5. The Final Rule’s Definition of Discrimination “On the Basis of Sex” Has Been Enjoined by Federal Courts.

In its Section 1557 Regulation, the Department interpreted the “sex” discrimination prohibited by Section 1557 to include discrimination on the basis of “gender identity.” 81 FR 31376, 31467 (definition of “on the basis of sex,” codified at 45 CFR 92.4). In particular, the Department took the view that one can identify as “male, female, neither, or a combination of male and female” and that this identification may differ from one’s “sex assigned at birth” because, according to the regulation, gender identity ultimately relies on a subjective “internal sense.” 81 FR at 31467; 45 CFR 92.4 (definition of “gender identity”). It then reasoned that Title IX’s prohibition of discrimination on the basis of sex (as incorporated by Section 1557) includes discrimination on the basis of pregnancy termination,³⁴ sex stereotyping,³⁵ and gender identity.³⁶

³⁴ The preamble to the Final Rule cites the Department’s Title IX regulation, which contains provisions on termination of pregnancy, but does not analyze this regulatory language in light of Title IX’s statutory provisions about abortion. *See* 81 FR at 31387 (citing 45 CFR 86.40(b)); *but see* 20 U.S.C. 1688 (“Nothing in this title shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities related to an abortion...”).

³⁵ The Final Rule defines “sex stereotypes” as “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. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gender expectations related to the appropriate roles of a certain sex.” 81 FR at 31468 (codified at 45 CFR 92.4).

³⁶ The Final Rule defines “gender identity” as “an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual’s sex assigned at birth.” 81 FR at 31467 (codified at 45 CFR 92.4). The Final Rule notes, in

Interpreting Section 1557, through Title IX, to prohibit gender identity discrimination was a relatively novel legal theory when the Department adopted the Final Rule. The theory, was not, and has not been, endorsed by the Supreme Court. *See, e.g., Baker v. Aetna*, 228 F. Supp. 3d 764, 768-69 (N.D. Texas 2017) (noting no controlling U.S. Supreme Court legal precedent recognizing gender identity as prohibited discrimination under Section 1557).

a. Background on Title IX of the Education Amendments

Title IX prohibits discrimination on the basis of sex in educational programs or activities that receive Federal financial assistance. Specifically, the statute states that “[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance” 20 U.S.C. 1681. The statute uses the word “sex” but not “sexual orientation” or “gender identity.” Although it does not contain an express definition of the term “sex,” additional provisions in Title IX use explicitly binary terms such as “men” and “women,” “father-son,” “mother-daughter,” “boys” and “girls,” “both sexes,” and “one sex” and “the other sex.”³⁷

the definition, that “the way an individual expresses gender identity is frequently called ‘gender expression,’ and may or may not conform to social stereotypes associated with a particular gender.” *Id.* The definition also notes that “[a] transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.” *Id.* The regulation requires covered entities to treat individuals “consistent with their gender identity” except that covered entities “may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual’s sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.” 45 CFR 92.206 and 92.207(b)(3).

³⁷Although Congress did not include a definition of the term “sex”, provisions in Title IX refer to “men” and “women,” “father-son,” “mother-daughter,” “boys” and “girls,” “both sexes,” and “one sex” and “the other sex” 42 U.S.C. 1681(a)(2)(“both sexes”), (a)(2)(“one sex” and “other sex”),

Congressional activity in this area suggests that “sex” under Title IX does not include sexual orientation or gender identity. *See Food & Drug Admin.v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 122 (2000) (when “Congress several times considered and rejected bills” that would have granted the agency authority, Congress “evidenced a clear intent to preclude a meaningful policymaking role for any administrative agency”). For example, in 2016, Senator Mazie Hirono introduced the Patsy T. Mink Gender Equity in Education Act, S. 3147 (114th Cong. 2016), to “support educational entities so that such entities have the support to fully implement [T]itle IX” and to define “sex discrimination” to include “[a]ctual or perceived sex, sexual orientation, gender, or gender identity.” *See also* H.R. 5682 (114th Cong. 2016) (companion measure introduced in the House of Representatives). However, there was no action on the Senate bill after it was referred to the Senate Committee on Health, Education, Labor and Pensions. Congress has repeatedly considered bills that would add the bases of sexual orientation or gender identity to other statutes that already prohibited discrimination on the basis of sex, but has done so in only limited instances.³⁸

Over the past three decades, Members of Congress have repeatedly proposed to amend the Civil Rights Act to add the words “sexual orientation” and “gender

(a)(6)(B)(“Men’s” and “Women’s”), (a)(6)(B)(“Boy” and “Girl”); (a)(7)(A)(“Boys” and “Girls”), (a)(7)(B)(i)(“Boys” and “Girls”), (a)(8)(“father-son”, “mother-daughter”), and (a)(8) (“one sex” and “other sex”). *See also* 42 U.S.C. 1681(a)(2)(6)(“fraternity” and “sorority”).

³⁸ 18 U.S.C. 249(c)(4) (the Matthew Shepard and James Byrd, Jr. Hate Crimes Prevention Act prohibits hate crimes which are based on “actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability”); 34 U.S.C. 12291(b)(13)(A) (the Violence Against Women Reauthorization Act (VAWA) prohibits discrimination on the basis of “actual or perceived...sex, gender identity... [or] sexual orientation”).

identity” as prohibited bases of discrimination, but as of the date of publication of this proposed rule, such measures have never become Federal law.³⁹

b. HHS’s Title IX Regulations

In 1975, the predecessor to HHS (the Department of Health, Education, and Welfare (HEW)) became the first agency to adopt Title IX implementing regulations. 40 FR 24128 (June 4, 1975). The agency received and considered more than 9,700 comments before issuing its final regulations, and Congress held six days of hearings to determine whether the regulations were consistent with the statute.⁴⁰ The regulations,⁴¹ like Title IX itself, included no explicit definition of “sex.”⁴² Like Title IX, however, the Title IX regulations do use explicitly binary terms such as “male and female” (§ 86.41(c)) and “one sex... [and] the other sex” (*passim*).

³⁹ Over the past three decades, the Employment Non-Discrimination Act (ENDA) has been introduced ten times in the U.S. House of Representatives, but ENDA, which would prohibit employment discrimination on the basis of sexual orientation and gender identity, has never proceeded out of committee in the House. *See* H.R. 4636 (103rd Cong. 1994); H.R. 1863 (104th Cong. 1995); H.R. 1858 (105th Cong. 1997); H.R. 2355 (106th Cong. 1999); H.R. 2692 (107th Cong. 2001); H.R. 3285 (108th Cong. 2003); H.R. 2015 (110th Cong. 2007); H.R. 2981 (111th Cong. 2009); H.R. 1397 (112th Cong. 2011); H.R. 1755 (113th Cong. 2013). The Equality Act has similarly been introduced in three successive sessions of Congress. *See* H.R. 3185 (114th Cong. 2015); S. 1828 (114th Cong. 2015); H.R. 2282 (115th Cong. 2017); S. 1006 (115th Cong. 2017); H.R. 5 (116th Cong.) (introduced Mar. 3, 2019). It did not proceed out of committee in the 114th and 115th Congresses, and it passed the House of Representatives on May 17, 2019. The Equality Act would amend the Civil Rights Act to include “gender identity” and “sexual orientation” in addition to “sex” as prohibited grounds of discrimination, and would also include a definition of the terms “sex” and “gender identity.”

⁴⁰ Subcommittee on Postsecondary Education of the House Committee on Education and Labor, Review of Regulations to Implement Title IX of Public Law 92-318 Conducted Pursuant to Sec. 431 of the General Education Provisions Act (94th Cong. June 17, 20, 23, 24, 25, 26, 1975); *see also* Title IX Common Rule, 65 FR 52857 (Sept. 29, 2000) (the HEW regulations were “the result of an extensive public comment process and congressional review”).

⁴¹ *See* 45 CFR part 86.

⁴² Consistent with the statutory language, the Title IX regulations used the same binary and biological language about sexes as found in Title IX, including “both sexes,” “the other sex,” and “boys” and “girls.” *See* 45 CFR 86.2(s), 86.7, 86.17(b)(2), 86.21(c)(4), 86.31(c), 86.32(b)(2) and (c)(2), 86.33, 86.37(a)(3), 86.41(b) and (c), 86.55(a), 86.58(a) and (b), 86.60(b), and 86.61.

When HHS interpreted “on the basis of sex” under Title IX through its Section 1557 regulation, HHS did not add the definition to its Title IX regulation. Neither did HHS amend its Title IX Regulation to adjust the references to “male and female” or “one sex... [and] the other sex” to conform to the novel definition in the Section 1557 regulation. *Compare* 81 FR 31467 (May 18, 2016) (Section 1557 Regulation) *with* 70 FR 24320 (May 9, 2005) (the last time HHS’s Title IX regulations were amended).

c. Need for Consistency Among Components of HHS

Since 2012, other components of the Department adopted an interpretation of sex different from the definition OCR adopted in the Section 1557 Regulation. The Department’s failure to address these other definitions in the Final Rule has resulted in substantial confusion and inconsistency.

In 2014, the National Institutes of Health (NIH) announced its policy that researchers seeking NIH grant funds should explain how differences between males and females on the basis of biology are factored into research designs, analyses, and reporting in clinical research as a biological variable.⁴³ This approach, according to NIH, acknowledged that research about male and female differences may be critical to the interpretation, validation, and generalizability of research findings and may inform clinical interventions. In 2017, NIH issued guidance to grant recipients about

⁴³ Janine A. Clayton and Francis S. Collins, *Policy: NIH to balance sex in cell and animal studies*, *Nature* (May 14, 2014) (discussing disease-causing effects of Y-chromosome genes as different from X-chromosome genes, and intrinsic sex differences of female and male cells *in vitro*), <https://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195>; NIH, *Consideration of Sex as a Biological Variable in NIH-Funded Research*, NOT-OD-15-102 (June 9, 2015), <https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html>.

this policy⁴⁴ and continues to fund research that uses “sex” as a biological variable.⁴⁵

Using sex as a biological variable addresses binary male/female differences found to impact the practice of medicine by influencing proper diagnosis, prognosis, and treatment of patients.⁴⁶ Medical research prior to and subsequent to the Section 1557 Regulation have addressed differences between males and females as binary and biological.⁴⁷

⁴⁴NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* (2017), https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.

⁴⁵Suk Kyeong Lee, *Sex as an important biological variable in biomedical research*, BMB Rep. 167 (Apr. 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5933211>; Terry Lynn Cornelison, *Considering Sex as a Biomedical Variable in Biomedical Research*, Gender and the Genome (June 1, 2017), <https://journals.sagepub.com/doi/pdf/10.1089/gg.2017.0006>; Inna Belfer, J. White, et al., *Considering sex as a biological variable (SABV) in research: a primer for pain investigators*, The Journal of Pain (Mar. 2018), [https://www.jpain.org/article/S1526-5900\(17\)31024-6/pdf](https://www.jpain.org/article/S1526-5900(17)31024-6/pdf).

⁴⁶Janine A. Clayton, *Applying the new SABV (sex as a biological variable) policy to research and clinical care*, Physiology and Behavior (Aug 17, 2017), <https://doi.org/10.1016/j.physbeh.2017.08.012>; see also Leah R. Miller, Cheryl Marks, et al., *Considering sex as a biological variable in preclinical research*, 31 Federation of American Societies for Experimental Biology Journal 29-34 (Sept. 2017) (defining “Sex” as “being XY or XX”), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6191005>.

⁴⁷See, e.g., Douglas C. Dean III, E. M. Planalp, et al., *Investigation of brain structure in the 1-month infant*, Brain Structure and Function 1-18 (Jan. 5, 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29305647> (finding differences between male and female infants at the age of 1 month, “[c]onsistent with findings from studies of later childhood and adolescence, subcortical regions appear more rightward asymmetric”); Wei Yang, Nicole M. Warrington, et al., *Clinically Important Sex differences in GBM biology revealed by analysis of male and female imaging, transcriptome and survival data*, Science Translational Medicine (Jan. 21, 2019), <https://www.ncbi.nlm.nih.gov/pubmed/30602536S> (identifying sex-specific molecular subtypes of glioblastoma); Stefan Ballestri, Fabio Nascimbeni, et al., *NAFLD as a Sexual Dimorphic Disease: Role of Gender and Reproductive Status in the Development and Progression of Nonalcoholic Fatty Liver Disease and Inherent Cardiovascular Risk*, Advances in Therapy (May 19, 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5487879>; Ester Serrano-Saiz, Meital Oren-Suissa, et al., *Sexually Dimorphic Differentiation of a C. elegans Hub Neuron Is Cell Autonomously Controlled by a Conserved Transcription Factor*, 27 Current Biology 199 (Jan. 5, 2017), <https://www.ncbi.nlm.nih.gov/pubmed/28065609>; Anke Samulowitz, Ida Gremyr, et al., *“Brave Men” and “Emotional Women”: A Theory-Guided Literature Review on Gender Bias in Health Care and Gendered Norms towards Patients with Chronic Pain*, Pain Research and Management (Feb. 25, 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29682130> (stating that “the response to opioid receptor antagonists may generate a difference between men’s and women’s experiences of pain”); Susan Sullivan, Anna Campbell, et al., *What’s good for the goose is not good for the gander: Age and gender differences in scanning emotion faces*, 72:3 Journals of Gerontology 441 (May 1, 2017), <https://www.ncbi.nlm.nih.gov/pubmed/25969472>; Ramona Stone and W. Brent Webber, *Male-Female Differences in the Prevalence of Non-Hodgkin Lymphoma*, 81 Journal of Environmental Health 16 (Oct. 2018).

NIH also funded conferences of mental health professionals who developed the latest clinical manual on the diagnosis of “gender dysphoria” that defines “sex” (as distinct from “gender identity”) in biological terms.⁴⁸ Specifically, the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) provides, “[t]his chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in this area. In this chapter, sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia.”⁴⁹

Additionally, NIH requires research grant applicants to consider sex as a biological variable “defined by characteristics encoded in DNA, such as reproductive organs and other physiological and functional characteristics.”⁵⁰ According to an NIH article, “[s]ex as a biological variable (SABV) is a key part of the new National Institutes of Health (NIH) initiative to enhance reproducibility through rigor and transparency. The SABV policy requires researchers to factor sex into the design, analysis, and reporting of vertebrate animal and human studies. The policy was implemented as it has become increasingly clear that male/female differences extend well beyond reproductive and hormonal issues. Implementation of the policy

⁴⁸ NIH sponsored thirteen scientific conferences that assisted in research evaluation by hundreds of mental health specialists for the American Psychiatric Association to produce the standard classifications of mental disorders of the *Diagnostic and Statistical Manual of Mental Disorders Handbook of Differential Diagnosis (DSM-5)*.

⁴⁹ Although the Section 1557 Final Rule proposed to address insurance coverage for care related to gender dysphoria on the basis of a sex discrimination theory, neither the Notice of Proposed Rulemaking in 2015 nor the Final Rule in 2016 referenced the DSM-5’s definition of the term “sex.” 81 FR 31429.

⁵⁰ NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* at 1 (2017), https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.

is also meant to address inattention to sex influences in biomedical research. Sex affects: cell physiology, metabolism, and many other biological functions; symptoms and manifestations of disease; and responses to treatment. For example, sex has profound influences in neuroscience, from circuitry to physiology to pain perception. Extending beyond the robust efforts of NIH to ensure that women are included in clinical trials, the SABV policy also includes rigorous preclinical experimental designs that inform clinical research.”

In 2014, the Department’s Office of Refugee Resettlement (ORR) published an Interim Final Rule⁵¹ which adopted a biologically based definition of “sex” that was distinct from gender identity, to implement section 1101(c) of the Violence Against Women Reauthorization Act of 2013.⁵² In setting forth standards and procedures to prevent, detect, and respond to sexual abuse and sexual harassment involving unaccompanied alien children in ORR’s care provider facilities, the rule defines “sex” as “a person’s biological status and is typically categorized as male, female, or intersex.” 45 CFR 411.5. The definition notes that “[t]here are a number of indicators of biological sex, including sex chromosomes, gonads, internal reproductive organs, and external genitalia.” *Id.* The regulation gives a separate definition for “gender identity” as “one’s sense of oneself as a male, female, or transgender.” *Id.* The rule then uses these terms differently, setting forth protections and policies concerning “sex,” distinct from those protections and policies

⁵¹ ORR Final Rule, Standards to Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children, 79 FR 77767 (Dec. 24, 2014).

⁵² See 127 Stat. 61 (Violence Against Women’s Act reauthorization).

concerning “gender” or “gender identity.”⁵³ The definitions section of the ORR regulation states “‘Gender’ refers to the attitudes, feelings, and behaviors that a given culture associates with a person’s biological sex.” 45 CFR 411.5 In the preamble to the rule, ORR added, “This term [‘gender’] is not to be confused with ‘sex,’ as defined [elsewhere in the rule].” 79 FR at 77771.

In 2015, the Office of the National Coordinator for Health Information Technology (ONC) promulgated regulations⁵⁴ that included standards and requirements for coding certain health data. The regulations contained data sets for “sex,” separate from those for “gender identity” and “sexual orientation.” *See* 45 CFR 170.207(n) (“sex”); 170.207(o) (“sexual orientation and gender identity”). In its preamble, ONC explained that it did not adopt a separate category for “assigned birth sex” because “we already require the capturing of birth sex as described under the “sex” section above.”⁵⁵ Furthermore, ONC stated that questions about patients’ gender identity and sexual orientation “have not yet been scientifically validated for

⁵³ *Compare, e.g.*, 45 CFR 411.14 (“Care provider facilities must not search or physically examine a UC for the sole purpose of determining the UC’s sex. If the UC’s sex is unknown, it may be determined during conversations with the UC, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical practitioner.”) *with* § 411.41(c) (“Only trained staff are permitted to talk with UCs to gather information about their sexual orientation or gender identity, prior sexual victimization, history of engaging in sexual abuse, mental health status, and mental disabilities for the purposes of the assessment required under paragraph (a) of this section.”).

⁵⁴ ONC Final Rule, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications, 80 FR 62601 (Oct. 16, 2015); *see also* 80 FR 76868 (Dec. 11, 2015) (making technical corrections and clarifications).

⁵⁵ 80 FR 62619. Requiring health care entities to code as male all persons who self-identify as male, regardless of biology, may lead to adverse health consequences. *See, e.g.*, Daphne Stroumsa, Elizabeth F.S. Roberts, *et al.*, “The Power and Limits of Classification – A 32 Year Old Man with Abdominal Pain,” *New England Journal of Medicine* (May 16, 2019), <https://www.ncbi.nlm.nih.gov/pubmed/31091369>; Marilyn Marchione, “Blurred Lines,” *Associated Press* (May 15, 2019), <https://apnews.com/b5e7bb73c6134d58a0df9e1cee2fb8ad> (identification of pregnant transgender person as male in medical records contributed to stillbirth of child).

use in health care settings” and, thus, it did not adopt them.⁵⁶ However, ONC added that, although not required, providers can separately code “gender identity”⁵⁷ and “sexual orientation”⁵⁸ if they opt to include such questions.⁵⁹

OCR itself has adopted different interpretations of “on the basis of sex” under Section 1557. In 2012, the then-OCR Director announced in a letter⁶⁰ that OCR was accepting and investigating complaints of discrimination on the basis of “actual or perceived sexual orientation or gender identity” under Section 1557. Three years later, OCR changed its position and declined to include sexual orientation (unlike gender identity) as a *per se* protected class throughout the Section 1557 rulemaking process. *See Proposed Rule*, 81 FR 54176 (Aug. 15, 2015) (“Current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions of sex discrimination”); *Final Rule*, 81 FR 31390 (May 18, 2016) (“OCR has decided not to resolve in this rule whether discrimination on the basis of an individual’s sexual orientation status alone is a form of sex discrimination.”). It appears that OCR’s letter in 2012 was the first time any HHS component departed from a binary and biological understanding of sex for purposes of sex discrimination and adopted a definition that included gender identity or sexual orientation.

⁵⁶ 80 FR at 62620.

⁵⁷ Options under the category “gender identity” were “Male”, “Female, transgender male/Trans man/Female-to-male,” “Transgender female/Trans woman/Male-to-female,” “Genderqueer, Neither exclusively male nor female,” “Additional gender category/(or other), please specify,” or “Decline to answer.”

⁵⁸ Options under the category “sexual orientation” were “Straight or heterosexual,” “Lesbian, gay, or homosexual,” “Bisexual,” “Something else, please describe,” or “Don’t know.”

⁵⁹ 80 FR 62620.

⁶⁰ See 81 FR 31387, n.57.

d. Pending Federal Litigation Over Section 1557 Regulation, Title IX, and Title

VII

In addition to *Franciscan Alliance* in the U.S. District Court for the Northern District of Texas and *Sisters of Mercy* in the U.S. District Court for the District of North Dakota, other Federal courts have gender identity discrimination cases, filed under Section 1557, pending on their dockets. See *Tovar v. Essentia Health*, 342 F. Supp. 3d 947 (D. Minn. Sept. 20, 2018) (on remand from 8th Cir.); *Boyden v. Conlin*, 341 F. Supp.3d 979 (W.D. Wis. 2018) (appealed to 7th Cir., No. 3:18-3408 and No. 18-3485, on Nov. 9, 2018); *Flack v. Wisconsin Department of Health Services*, 328 F. Supp.3d 931(W.D. Wis. 2018) (pending motion for class certification); *Smith v. Highland Hospital of Rochester*, No. 17-CV-6781-CJS (W.D.N.Y. filed Oct 2, 2018) (appealed to 2d Circuit on Nov. 6, 2018); *Prescott v. Rady Children’s Hospital-San Diego*, 265 F.Supp.3d 1090 (S.D. Cal. Sept. 27, 2017) (protective order granted on Nov. 6, 2018); *Edmo v. Idaho Dept. of Correction*, No. 1:17-cv-00151, 2018 WL 2745898 (D. Id. filed Oct. 9, 2018) (motion to stay pending February 13, 2019); *Enstad v. Peacehealth*, No. 2:17-cv-01496-RSM (W.D. Wash. filed Oct. 5, 2017) (granted stay of litigation on Sept. 24, 2018); *Robinson v. Dignity Health*, No. 16-CV-3035 YGR, 2016 WL 7102832 (N.D. Cal. filed Dec. 6, 2016) (on remand from U.S. Supreme Court).

Some Federal courts have declined to recognize gender identity discrimination claims under Title IX, and instead deferred to U.S. Supreme Court to settle the legal question. See, e.g., *Evancho v. Pine-Richland School District*, 237 F. Supp.3d 267, 299 (W.D. Pa. February 27, 2017) (“what makes the current legal

landscape even more unsettled is that the Supreme Court is currently poised to grapple with these very issues”). While four appellate courts have addressed the issue,⁶¹ a large volume of district court opinions have been inconsistent on the issue. *See Texas v. United States*, 201 F. Supp. 3d 810 (N.D. Tex. 2016) (holding that Title IX does not prohibit discrimination based on gender identity or transgender status); *Johnston v. Univ. of Pittsburgh*, 97 F. Supp. 3d 657 (W.D. Pa. 2015); *but see Adams v. School Board of St. Johns County*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018) (recognizing gender identity discrimination claim under Title IX); *A.H. v. Minersville Area School District*, 290 F. Supp. 3d 321 (M.D. Pa. 2017). Appellate courts have also been split over the legal question whether discrimination on the basis of gender identity is prohibited by Title VII. *Compare Etsitty v. Utah Transit Auth.*, 502 F.3d 1215, 1220-1221 (10th Cir. 2007) with *Mitchell v. Kallas*, No. 15-cv-108 (7th Cir. 2018). On April 22, 2019, the U.S. Supreme Court granted three petitions for writs of certiorari, raising the question whether Title VII’s prohibition on discrimination on the basis of sex also bars discrimination on the basis of gender identity or sexual orientation.⁶²

⁶¹ *See, e.g., Doe ex rel. Doe v. Boyertown Area Sch. Dist.*, 893 F.3d 179 (3d Cir.), slip op. 23-31, *vacated on reh’g*, 897 F.3d 515 (3d Cir.), and *superseded by* 897 F.3d 518 (3d Cir. 2018); *Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1046-54 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018); *G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, 822 F.3d 709, 720-723 (4th Cir. 2016), *vacated and remanded*, 137 S. Ct. 1239 (2017); *Dodds v. U.S. Dept. of Education*, 845 F.3d 217 (6th Cir. 2016). Portions of two of these opinions have been vacated. *See Gloucester Cnty. Sch. Bd. v. G.G. ex rel. Grimm*, 137 S. Ct. 1239 (2017) (vacating court of appeals’ decision in light of agency guidance); *Doe ex rel. Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 533-36 (3d Cir. 2018) (superseding opinion omitting portion of original opinion discussed in the petition, which was vacated on rehearing); *cf. Doe*, 893 F.3d 179, slip op. 23-31 (vacated opinion).

⁶² *Bostock v. Clayton County*, 723 Fed. Appx. 964 (11th Cir. 2018), *cert. granted*, No. 17-1618 (U.S. Apr. 22, 2019); *Altitude Express, Inc. v. Zarda*, 883 F.3d 100 (2d Cir. 2018), *cert. granted*, No. 17-1623 (U.S. Apr. 22, 2019); *Equal Employment Opportunity Commission v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F.3d 560 (6th Cir. 2018), *cert. granted*, No. 18-107 (U.S. Apr. 22, 2019), https://www.supremecourt.gov/orders/courtorders/042219zor_9olb.pdf.

Because Title IX adopts the substantive and legal standards of Title VII,⁶³ a holding by the U.S. Supreme Court on the definition of “sex” under Title VII will likely have ramifications for the definition of “sex” under Title IX, and for the cases raising sexual orientation or gender identity claims under Section 1557 and Title IX which are still pending in district courts.⁶⁴

e. HHS’s Inconsistency with Other Federal Agencies

From 1972 to the present, no Title IX regulation from any agency explicitly defined “sex” to include “gender identity.” All of the Title IX regulations of all agencies which adopted such regulations – including, as noted above, HHS’s Title IX regulations – use the term in a binary and biological sense, and include phrases such as “male and female,” and “one sex” and “the other sex.”⁶⁵ Currently, HHS is the only Federal agency with a regulation defining “sex” under Title IX (in its Section 1447 Regulation) as inclusive of gender identity. However, starting in 2012, two other agencies—the Department of Justice (DOJ), and the Department Education (ED)—took enforcement actions, issued guidance, or took litigating positions that

⁶³ See DOJ, Title IX Legal Manual (August 6, 2015), <https://www.justice.gov/crt/title-ix>.

⁶⁴ Compare *Etsitty v. Utah Transit Auth.*, 502 F.3d 1215 (10th Cir. Sept. 20, 2007) (Title IX does not prohibit gender identity discrimination); and *Texas v. United States*, 201 F. Supp. 3d 810 (N.D. Tex. Aug. 21, 2016) with *Doe ex rel. Doe v. Boyertown Area Sch. Dist.*, 893 F.3d 179 (3d Cir.), slip op. 23-31, vacated on reh’g, 897 F.3d 515 (3d Cir.), and superseded by 897 F.3d 518 (3d Cir. 2018); *Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1046-1054 (7th Cir. 2017) (interpreting Title IX and Equal Protection Clause), cert. dismissed, 138 S. Ct. 1260 (2018); and *G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, 822 F.3d 709, 720-723 (4th Cir. 2016), vacated and remanded, 137 S. Ct. 1239 (2017).

⁶⁵ See, e.g., Department of Education Title IX regulation at 34 CFR 106.2(s), 106.7, 106.17(b)(2), 106.21(c)(4), 106.31(c), 106.32(b)(2) and (c)(2), 106.33, 106.37(a)(3), 106.41(b) and (c), 106.55(a), 106.58(a) and (b), 106.60(b), and 106.61; Department of Justice Title IX regulation at 28 CFR 54.105, 54.130, 54.230(b)(2), 54.235(b)(3), 54.300(c)(4), 54.400(c), 54.405(b)(2) and (c)(2), 54.410, 54.430(a)(3), 54.450(b) and (c)(2), 54.520(a), 54.535(a) and (b), 54.545(b), and 54.550. See also DOJ Coordination and Compliance Division, Title IX Regulations by Agency, https://www.justice.gov/crt/fcs/Agency_Regulations#2.

discrimination on the basis of sex under certain anti-discrimination statutes included “gender identity.” See ED, Office for Civil Rights, Questions and Answers in Title IX and Single Sex Elementary and Secondary Classes and Extra curricular Activities (2014)⁶⁶; ED and DOJ joint Dear Colleague Letter on Transgender Students (May 13, 2016) (Title IX guidance); Complaint, *United States v. McCrory*, No. 5:16-cv-238-BO (M.D.N.C. filed May 9, 2016) (DOJ Title IX lawsuit challenging a North Carolina law concerning transgender access to intimate facilities at State university). The Department proposed (and then finalized) its definition to be consistent with the policy positions, sub-regulatory guidance, and enforcement actions of ED and DOJ.⁶⁷

The earlier interpretations have now been taken under review, dismissed, preliminarily enjoined, or revoked outright. See *Franciscan Alliance, Inc., et al. v. Burwell, et al.*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016) (nationwide preliminary injunction against the Section 1557 regulation); *Texas, et al. v. United States, et al.*, 201 F. Supp. 3d 810, 836 (N.D. Tex. 2016) (preliminarily enjoining ED’s Title IX interpretation); Dear Colleague Letter (Feb. 22, 2017) (ED and DOJ’s withdrawal of the May 13, 2016 Dear Colleague Letter); Stipulated Joint Notice of Dismissal, *United States v. State of North Carolina*, No. 1:16-cv-425 (M.D.N.C. May 4, 2017) (dismissing, with prejudice, the DOJ lawsuit challenging the North Carolina law).

As noted above, in *Franciscan Alliance*, DOJ submitted a brief on behalf of HHS, in response to plaintiffs’ motions for summary judgment, on April 5, 2019. The

⁶⁶ <http://www2.ed.gov/about/offices/list/ocr/docs/faqs-title-ix-single-ex201412.pdf>.

⁶⁷ See 81 FR at 31388-31389.

brief stated that Section 1557’s prohibition on sex discrimination “unambiguously excludes discrimination on the basis of gender identity.”⁶⁸

The Department proposes to repeal the novel definition of “sex” in the Section 1557 regulation in order to make the Department’s regulations implementing Title IX through the Section 1557 Regulation more consistent with the Title IX regulations of other Federal agencies. The Department further believes this proposed rule avoids different interpretations of the same statute by multiple agencies, and promotes consistent expectations and enforcement.

f. Need for Consistency with the Department of Justice on Implementation and Enforcement of Nondiscrimination Laws

In 1980, the President delegated to the Attorney General the responsibility to lead the coordination of consistent and effective implementation of cross-cutting nondiscrimination laws, including Title VI, Title IX, and Section 504.⁶⁹ The Department, along with each other Executive Agency, is required to cooperate with DOJ and issue its implementing regulations consistent with the requirements prescribed by the Attorney General, unless prohibited by law.⁷⁰

In court briefs and otherwise on behalf of the United States, DOJ has stated that the ordinary meaning of the word “sex” for purposes of Federal nondiscrimination laws does not encompass sexual orientation or gender identity. On April 5, 2019, DOJ filed a brief on behalf of HHS in the *Franciscan Alliance* case

⁶⁸ See Defendant’s Memorandum in Response to Plaintiffs’ Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-O, p. 11 (N.D. Tex, filed April 5, 2019).

⁶⁹ Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, Secs. 1-201(a) through (c), 45 FR 72995 (Nov. 2, 1980).

⁷⁰ Executive Order 12250 at Secs. 1-401 through 1-402.

stating that “the relevant provisions of Title IX and Section 1557 unambiguously exclude gender-identity discrimination.”⁷¹ Similarly, in a July 26, 2017 *amicus curiae* brief in a Second Circuit case regarding the prohibition of sex discrimination in employment under Title VII of the Civil Rights Act of 1964, DOJ stated, “[i]n common, ordinary usage in 1964—and now, for that matter—the word ‘sex’ means biologically *male* or *female*.”⁷²

Consistent with this position, a few months later, the Attorney General issued a memorandum stating that “‘sex’ is ordinarily defined to mean biologically male or female” and that “Congress has confirmed this ordinary meaning by expressly prohibiting, in several other statutes, ‘gender identity’ discrimination, which Congress lists in addition to, rather than within, prohibitions on discrimination on the basis of ‘sex’ or ‘gender.’”⁷³ The memorandum concluded, “Title VII’s prohibition on sex discrimination encompasses discrimination between men and women but does not encompass discrimination based on gender identity *per se*, including transgender status. Therefore, as of the date of this memorandum ... the Department of Justice will take that position in all pending and future matters....”

DOJ also took that position on October 24, 2018, when it submitted a brief to the U.S. Supreme Court in another Title VII case in which a petition for a writ of certiorari was filed. DOJ argued that “Title VII does not define the term ‘sex,’ so the

⁷¹ See Defendant’s Memorandum in Response to Plaintiffs’ Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-O, p. 14 (N.D. Tex. filed April 5, 2019).

⁷² See also DOJ Brief for the United States as *Amicus Curiae*, p. 4, in *Zarda v. Altitude Express, Inc.*, 883 F.3d 100 (2d Cir. July 26, 2017) (quoting dissent in *Hively v. Ivy Tech Community College*, 853 F.3d 339, 362 (7th Cir. 2017)); DOJ Brief in Support of Defendants’ Motion to Dismiss at 2-6, *U.S. Pastor Council v. EEOC*, No. 4:18-cv-00824-O (N.D. Tex. Dec. 17, 2018).

⁷³ Memorandum of the Attorney General (Oct. 4, 2017), <https://www.justice.gov/ag/page/file/1006981/download>.

term should 'be interpreted as taking [its] ordinary, contemporary, common meaning.' When Title VII was enacted in 1964, 'sex' meant biological sex; it 'refer[red] to [the] physiological distinction[]' between 'male and female.' Title VII thus does not apply to discrimination against an individual based on his or her gender identity. Notably, Congress has specifically prohibited discrimination based on 'gender identity' in other statutes, as a separate protected category in addition to 'sex' or 'gender.' It has not included similar language in Title VII as originally enacted in 1964 or in any amendment in the 54 years since."⁷⁴

Nevertheless, because the Section 1557 Regulation's gender identity provisions remain, public confusion persists. To ensure that its civil rights regulations are consistent with the views of the Department of Justice, other Federal agencies, and internally, the Department proposes to repeal the definition of "on the basis of sex" that had been adopted in its Section 1557 Final Rule. Because of the likelihood that the Supreme Court will be addressing the issue in the near future,⁷⁵ the Department declines, at this time, to propose its own, definition of "sex" for purposes of discrimination on the basis of sex in the regulation.

g. Sensitive Balancing of Competing Interests at the Local Level

The adoption of a definition of "sex" in the Section 1557 Regulation may stifle the ability of States, local governments, and covered entities to set their own policies

⁷⁴ DOJ, Brief for the Federal Respondent in Opposition to Petition for Writ of Certiorari in *R.G. & G.R. Harris Funeral Homes, Inc. v. Equal Employment Opportunity Commission, et al.*, No. 18-107, 16-18 (Oct. 2018) (citations omitted).

⁷⁵ See *Bostock v. Clayton County*, 723 Fed. Appx. 964 (11th Cir. 2018), *cert granted*, No. 17-1618 (U.S. Apr. 22, 2019); *Altitude Express, Inc. v. Zarda*, 883 F.3d 100 (2d Cir. 2018), *cert granted*, No. 17-1623 (U.S. Apr. 22, 2019); *Equal Employment Opportunity Commission v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F.3d 560 (6th Cir. 2018), *cert granted*, No. 18-107 (U.S. Apr. 22, 2019), https://www.supremecourt.gov/orders/courtorders/042219zor_9olb.pdf.

and balance multiple competing interests on questions related to gender dysphoria. Because Title IX and Section 1557 get their constitutional authority from the Spending Clause, according to the Supreme Court, it is appropriate that it be exercised with respect for State sovereignty:

[L]egislation enacted pursuant to the spending power is much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions. The legitimacy of Congress' power to legislate under the spending power thus rests on whether the State voluntarily and knowingly accepts the terms of the "contract." See *Steward Machine Co. v. Davis*, 301 U. S. 548, 585-598 (1937); *Harris v. McRae*, 448 U. S. 297 (1980). There can, of course, be no knowing acceptance if a State is unaware of the conditions or is unable to ascertain what is expected of it. Accordingly, if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously. Cf. *Employees v. Department of Public Health and Welfare*, 411 U. S. 279, 285 (1973); *Edelman v. Jordan*, 415 U. S. 651 (1974). By insisting that Congress speak with a clear voice, we enable the States to exercise their choice knowingly, cognizant of the consequences of their participation.

Pennhurst State School and Hospital v. Halderman, 451 U.S. 1, 17 (1981); see also *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 588 (2012) ("Congress has no authority to order the States to regulate according to its instructions. Congress may offer the States grants and require the States to comply with accompanying conditions, but the States must have a genuine choice whether to accept the offer") (opinion of Roberts, C.J., joined by Breyer and Kagan, JJ.). The Department's broad reinterpretation of "sex" under Title IX affected States' ability to accept these restrictions knowingly as they came long after states became heavily reliant on the continued receipt of Federal funds subject to Title IX requirements.

This proposed rule would significantly restore the ability of States to establish policies in this area, based on their weighing the competing interests at

stake. This proposed rule is not intended to remove any protection that Congress has provided by statute, including Title IX, or to deny States the ability to provide protections that exceed those required by Title IX. Rather, the proposed rule would ensure that the Department's Title IX and corresponding Section 1557 regulations follow the will of Congress with respect to the States by not expanding Title IX's definition of "sex" beyond the statutory bounds.

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

The Department has determined that the Section 1557 Regulation imposed substantially larger regulatory burdens than predicted, a result inconsistent with the policies of this Administration. In his first day in office, President Donald Trump issued Executive Order 13765, identifying it as Administration policy to "minimize the unwarranted economic and regulatory burdens of the [Patient Protection and Affordable Care] Act, and prepare to afford the States more flexibility and control to create a more free and open healthcare market." This Executive Order states that "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [PPACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [PPACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, [or] purchasers of health insurance." President Trump has also issued two further

Executive Orders directing executive agencies to relieve the regulatory burden and reduce regulatory costs across the Federal government.⁷⁶

1. The Section 1557 Regulation Imposed Substantially Higher Regulatory Costs Than Predicted.

The Department has concluded, based on its independent assessment of the evidence, that the costs and burdens imposed by the Section 1557 Regulation are substantially larger than originally anticipated. The Final Rule requires covered entities to post and disseminate to beneficiaries, enrollees, and the public, detailed notices of nondiscrimination that include information on how individuals with disabilities may receive auxiliary aids and services and how LEP individuals may receive translated documents or oral interpretation. 45 CFR 92.7. The Department estimated that this notice requirement would impose approximately \$3.6 million of costs in the first year of compliance and zero for the following four years. In calculating this cost, the Department counted the employee time required to initially download, print, and post notices in public areas, but did not count the recurring costs of paper, ink/toner, and additional postage for the required initial or subsequent mailings of these notices. 81 FR 31453, 31458.

The Final Rule additionally requires covered entities to provide to beneficiaries, enrollees, and others, “taglines” describing the availability of free language assistance services. The Final Rule requires these taglines be written in “at least the top 15 languages” spoken by LEP individuals in the relevant State or States.

⁷⁶ Executive Order 13771 on Reducing Regulation and Controlling Costs (Jan. 30, 2017); Executive Order 13777 on Enforcing the Regulatory Reform Agenda (Feb. 24, 2017); *see also* Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

45 CFR 92.8(d)(1). The Department estimated that the taglines requirement would cost the same as the notice of nondiscrimination requirement, namely, \$3.6 million in the first year and zero over the following four years. 81 FR 31453, 31458. Again, as with notices, the Department counted the employee time required to initially download, print, and post taglines, but did not count the recurring costs of paper, ink/toner, and additional postage for the required initial or subsequent mailings of taglines. 81 FR 31453.

The Department did not fully appreciate the volume of mail inserts the combined notice and tagline provisions would require. The Final Rule requires notices of nondiscrimination and taglines be appended to all “significant” publications and communications (bigger than a postcard or brochure) sent by covered entities to beneficiaries, enrollees, applicants, or members of the public. 45 CFR 92.8(f)(1). The Final Rule’s preamble explained that “significant communications” include “not only documents intended for the public . . . but also written notices to an individual, such as those pertaining to rights or benefits.” 81 FR 31402. Many health insurance issuers reasonably interpreted the Section 1557 Regulation as requiring that they provide the notice and taglines to their subscribers in nearly every written communication, including every time the issuer processes a claim and, as a consequence, issues a beneficiary an Explanation of Benefits.

Many of these matters were discussed in DOJ’s 2002 and HHS’s 2003 LEP guidance documents. The LEP guidance documents flagged concerns about “unrealistic” interpretations of translating written materials into languages when recipients serve communities in large cities or across the country and serve LEP

persons who speak dozens and sometimes over 100 different languages. 67 FR 41455, 41463 (June 18, 2002) (DOJ guidance); 68 FR 47311, 47319 (Aug. 8, 2003) (HHS guidance). Furthermore, with the recognition that there could be large numbers of documents in need of translation into dozens of languages, the LEP guidance documents advised that recipients could start with several of the more frequently encountered languages and set benchmarks for continued translations into the remaining languages over time. 67 at 41463 (DOJ); 68 FR at 47319 (HHS). By contrast, the Section 1557 Regulation set an effective date of July 18, 2016—only 60 days after promulgation of the final rule. The Section 1557 Regulation used the vague term “significant” to identify documents to which providers must append translated tagline notices. *See* 45 CFR 92.8(g). However, the Department’s long-standing LEP guidance discussed translation of “vital” documents, with the acknowledgement that “[c]lassifying a document as vital or non-vital is sometimes difficult” because the health care context is so fact-specific, depending on “the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner.” 68 FR at 47318 (HHS guidance).

In practice, the notices and taglines requirement results in the inclusion of one to two sheets of paper (which may be double-sided) per each significant communication mailed by a covered entity.

Data collected from covered entities, and the Department’s independent analysis, illustrate the financial impact of the notice and tagline requirements. One covered health insurance issuer, which sends over 42 million Explanations of

Benefits for one of its health plans to enrollees each year, states that it was required to add 2-5 pages of disclosure content to each letter or document, and estimates the incremental cost of printing, paper, and postage alone to be approximately \$8 million per year.⁷⁷ That covered health insurance issuer also reported that another of its health plans, which communicates with enrollees 50 to 90 times per year, estimated that it is spending approximately \$14 million annually on printing and postage for notice and tagline requirements.⁷⁸ A third plan reported that its costs for taglines were \$802,000 for the last quarter of 2016 and were projected to be \$2.4 million in 2017.⁷⁹ Another large plan estimates it will spend \$4-5 million per year to comply with these requirements.⁸⁰

A pharmacy benefit managers (PBM) trade association has reported similar effects of the Section 1557 Regulation. It estimates that PBMs process over three billion prescriptions per year, with each prescription requiring multiple “significant” communications be sent to beneficiaries (such as explanations of benefits, refill reminders, drug safety information, and other notices), many of which are sent by mail. The trade association estimates that this amounts to between 1 and 4.8 billion notices and taglines mailed per year at approximately \$0.50 to \$1 in additional printing and postage costs per communication. Thus, according to the trade association, these requirements have cost PBMs from \$500 million to nearly \$5

⁷⁷ Source: Aetna health plan representatives (April 13, 2017).

⁷⁸ Source: Aetna health plan representatives (May 1, 2017).

⁷⁹ Source: Aetna (April 10, 2017).

⁸⁰ Source: UnitedHealth Group (April 10, 2017).

billion per year.⁸¹ The high costs that health insurance issuers, health plans, and the members of a PBM trade association have reported about the costs resulting from the notice and tagline provisions of the Final Rule prompted the Department to reevaluate the requirement and its associated benefits and burdens.

As discussed further in the Regulatory Impact Analysis of this proposed rule, and based on the Department's independent analysis, the Department concludes that its original assessment of \$7.2 million in one-time notice and tagline-related costs underestimated the actual costs associated with including nondiscrimination notices and taglines in significant communications and publications.

The Department now estimates that the burden from the notice and taglines requirement ranges from \$147 million (low-end) to \$1.34 billion dollars (high-end) in annual costs before accounting for electronic delivery, as described below. These estimates are a function of multiplying the low and high per-unit cost of including a nondiscrimination notice and tagline insert (\$0.035/per unit to \$0.32/per unit) by the volume of significant communications and publications to which covered entities are required to attach the notice and taglines. The Regulatory Impact Analysis explains the calculations underlying these estimates in detail. The Department uses an average of the low- and high-end estimates, and adjusts for electronic delivery, to arrive at an average savings of \$0.632 billion per year which totals approximately \$3.16 billion over five years. The Regulatory Impact Analysis explains the assumptions, rationale, and calculations for this weighted average.

2. The Section 1557 Regulation's Burdens Are Not Justified by Need.

⁸¹ Source: Pharmaceutical Care Management Association (May 2, 2017).

The Department does not believe that the regulatory burdens of the Section 1557 Regulation, either as originally anticipated or as now more correctly estimated, are justified. The Department stated in the Final Rule that, apart from burdens related to the Final Rule’s definition of discrimination “on the basis of sex” and provisions concerning language access plans,⁸² “we do not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the regulation” because the Final Rule applies “pre-existing requirements” that have applied to regulated entities “for years.” 81 FR 31446. Indeed, the Department noted in the preamble to the Final Rule that, following the passage of Section 1557 in 2010, the Department’s Office for Civil Rights (OCR) complaint workload had increased only “slightly.” 81 FR 31458.

These facts call into question the need for both the \$942 million in costs to the public over five years that the Department originally anticipated, 81 FR 31459, and the additional approximately \$3.2 billion in notice and tagline compliance costs of which the Department is now aware.

Several factors suggest that the extraordinary burdens imposed by the notice and tagline requirements in particular are not justified by need. First, those requirements are difficult for covered entities to implement because of other differing and overlapping requirements already imposed by the Federal government

⁸² Language access plans are meant to assist covered entities in fulfilling their obligations to provide LEP individuals meaningful access to services provided by the covered entity. Although the Final Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director “shall” take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). The Department anticipated that 50% of covered entities would develop and implement a language access plan following issuance of the Final Rule. 81 FR 31454.

(with respect to Federal health care programs such as Medicare), and by many States (with respect to State-regulated health insurance), concerning language access.⁸³

Second, the Department has heard from multiple stakeholders that the repetitive nature of the notices and taglines in communications and publications dilutes the message contained in significant communications to the point that some recipients may be disregarding the information entirely.⁸⁴

Third, the Department has learned that many beneficiaries of Federal and other health programs do not want to receive extra pages of information they have

⁸³ *E.g.*, 42 U.S.C. 300gg-15(b)(2) and 300gg-19(a)(1)(B) (requiring standards for ensuring that the Summaries of Benefits and Coverage and certain notices are provided in a culturally and linguistically appropriate manner); 42 U.S.C. 1396d(p)(5)(A) (requiring HHS to distribute to States an application form for Medicare cost-sharing in English and 10 non-English languages); 26 CFR 1.501(r)-4(a)(1), (b)(5)(ii) (requiring a hospital organization to translate certain documents, among other requirements, to qualify for a tax-exempt status with respect to a hospital facility); 42 CFR 422.2262(a)(1)-(2) and 422.2264(e) (setting forth Medicare Advantage marketing requirements, which include requiring Medicare Advantage organizations to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area), § 423.2262(a)(1)-(2) and § 423.2264(e) (setting forth Medicare Part D marketing requirements, which include requiring Part D plan sponsors to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area); 45 CFR 155.205(c)(2)(iii)(A) (Marketplaces must post taglines on their websites and include taglines in documents “critical for obtaining health insurance coverage or access to health care services through a QHP”); 45 CFR 147.136(e)(2)(iii) and (e)(3), and 147.200(a)(5) (requiring taglines in languages in which 10% of individuals with limited English proficiency (LEP) county-wide are exclusively literate on internal claims and appeals notices and on an issuer’s Summary of Benefits and Coverage); 42 CFR 435.905(b)(3) (requiring individuals to be “informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services”); 42 CFR 457.340(a) (applying certain Medicaid requirements, including § 435.905(b)(3), which requires individuals to be “informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services”); 210 Illinois Cons. Stat. 87/1 (Illinois Language Assistance Act).

⁸⁴ Sources: Aetna, “Member Reactions to 1557 Taglines” (Apr. 2017); American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017); Pharmaceutical Care Management Association (May 2, 2017).

seen many times before out of environmental concerns or annoyance.⁸⁵ Aetna, one of the largest health insurance issuers in the United States, surveyed 322 enrollees by showing them a sample document with 4 pages of taglines; 75% of the enrollees reacted negatively (referring to the taglines as “wasteful,” “confusing,” “unintelligible,” “incomprehensible,” “inefficient,” among others), 50% said they would be less likely to carefully read documents from their insurer if they had taglines, and about one third said they would be less likely to open mail from an insurer if taglines were included in each document.⁸⁶

Fourth, the Department has received little evidence of more beneficiaries seeking language assistance as a result of the requirements that caused these increased burdens. Health plans report, anecdotally, that there has been no increase in the number of calls to their language lines requesting oral interpretation or written translation services since the notice and tagline requirements became effective in October 2016.⁸⁷ One plan reported lower numbers after the tagline requirement—it received 98,800 calls during the period between January and March 2016, but only 91,800 during the same time period in 2017.⁸⁸ Since the Final Rule, some pharmacy benefit managers report having received a handful of calls to their anti-discrimination grievance line, some have noticed an increase in their translation line call volume, some have noticed no change in call volume, and others have seen a decrease, but they report that, as a group, they have received

⁸⁵ Sources: Aetna (May 1, 2017); Pharmaceutical Care Management Association (Mar. 27, 2017); American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017).

⁸⁶ Source: Aetna, “Member Reactions to 1557 Taglines” (Apr. 2017).

⁸⁷ Sources: Pharmaceutical Care Management Association (Mar. 27, 2017); American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017).

⁸⁸ Source: Aetna (May 1, 2017).

significantly more complaints about providing too many notices, as compared to requests for translation assistance.⁸⁹

Fifth, the Department has found little evidence showing that repeatedly mailing all beneficiaries taglines with 15 or more languages is an efficient use of covered entities' resources when the overwhelming majority of beneficiaries speak English (with Spanish being a distant second). According to Census statistics, as of 2015, over three-quarters (79%) of the U.S. population over age 18 speaks only English at home, followed by Spanish (12.5%).⁹⁰ Additionally, of persons selecting a language preference when registering for coverage on the HealthCare.gov platform for 2017, 89.93% selected English, followed by 8.36% who selected Spanish.⁹¹ This data suggests that, for the large majority of people who receive them, the required language tagline mailings provide little to no benefit (and potentially impose burdens) because they are already proficient English speakers with little need for, and no entitlement under the law to, translation services.

Sixth, confusion over the notices has resulted in an increased volume of mistaken inquiries on the Department's public phone line.⁹² OCR's toll-free phone number, available to file civil rights complaints, is listed at the bottom of the Notice

⁸⁹ Source: Pharmaceutical Care Management Association (Mar. 27, 2017).

⁹⁰ U.S. Census Bureau, American FactFinder, "B16007: Age by Language Spoken at Home for the Population 5 Years and Over," 2011 - 2015 American Community Survey (2017), https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US.

⁹¹ CMS, "Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period," (April 2017), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf>. California and New York were not included in the analysis as they do not use the HealthCare.gov platform.

⁹² Between November 26, 2018 and April 2, 2019, OCR's Call Center received 983 calls on the complaint line from individuals who actually wanted to speak to their insurance company, not OCR, in order to raise billing questions, report a change of address, request a replacement insurance card, seek a reimbursement check, or make a payment.

of Nondiscrimination. *See* Appendix A to Part 92 (Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination Is Against the Law). However, recipients of the notices often misunderstand it to be the phone number to call when they have questions to ask their health insurance issuer or health care provider. The majority of phone calls to the OCR complaint line do not concern civil rights matters at all. This experience indicates that many members of the public do not fully read the non-discrimination notice or are confused because it is attached to other information sent to them by their providers or issuers. The result has been a significant waste of OCR resources with respect to its complaint line and a commensurate waste of time for callers.

The Department's proposal to substantially replace the Section 1557 Regulation with the existing framework for protection of civil rights laws, while expressly addressing language access issues in this proposed rule, will better strike the balance between the government's interest in ensuring meaningful access to covered healthcare programs for LEP individuals and the burdens imposed on regulated entities in support of that interest.

III. Nondiscrimination in Health Programs or Activities

This proposed rule would substantially replace the Section 1557 Regulation. The provisions proposed for retention, revision, and repeal are as follows:

A. Provisions of the Proposed Section 1557 Rule at 45 CFR Part 92

The proposed rule would more faithfully fulfill the Department's congressional mandate. In Section 1557 of the PPACA, Congress applied long-

standing nondiscrimination requirements to any health programs or activities that receive Federal financial assistance, or programs or activities administered by an Executive agency under Title I of the PPACA or any entity established under such Title I. It did so by cross-referencing the categories of protected classifications listed in those longstanding civil rights laws, namely, discrimination on the basis of race, color, national origin, sex, age, or disability. To ensure compliance, Congress dictated that “[t]he enforcement mechanisms provided for and available under” such laws “shall apply for purposes of violations of” Section 1557. The Department now proposes to fulfill this Congressional mandate by applying the enforcement mechanisms already provided for, and available under, existing statutes and their implementing regulations, including the rights and remedies under such laws.

Based on its review, and the preliminary injunction issued by the court in *Franciscan Alliance* that held parts of the Final Rule exceeded the Department’s authority under the PPACA, the Department has determined that (in addition to exceeding its statutory authority) parts of the regulation are duplicative, unduly burdensome, and confusing to the regulated community. This proposed rule, accordingly, would substantially replace 45 CFR part 92 with provisions in keeping with the plain language of Section 1557, while continuing to codify certain provisions regarding covered entities’ obligations with respect to language and disability access. This will ensure better compliance with the mandates of Congress, avoid further litigation, relieve regulatory burdens, reduce confusion, reduce uncertainty about the scope of Section 1557, promote substantive compliance, and improve the consistency of regulatory requirements between entities required to

comply with the civil rights laws as a result of Section 1557 and those directly subject to only to the underlying civil rights laws.

The proposed rule would be divided into two subparts: Subpart A on General Provisions (consistent with the current regulation), and Subpart B on Specific Applications to Health Programs or Activities. The Department proposes to replace §§ 92.1 through 92.3, 92.5, 92.6, and 92.101 of the current rule with provisions addressing Section 1557's purpose, nondiscrimination requirements, scope of application, enforcement mechanisms, relationship to other laws, and meaningful access for LEP individuals.

The Department's proposal does not change the provision to submit assurances of compliance with Section 1557 at § 92.5, designated as § 92.4. In addition, the Department would retain, but redesignate (to adjust to the proposed restructuring in the rule) the provisions on voluntary acceptance of language assistance services (§ 92.201(g)), effective communication for individuals with disabilities (§ 92.202), accessibility of buildings and facilities (§ 92.203), accessibility of information and communication technology (§ 92.204), and the requirement to make reasonable modifications (§ 92.205).

Although the proposed rule would eliminate the definitions section in the Section 1557 Regulation, the Department proposes to retain many key definitions explicitly in other sections or through incorporation by reference to relevant statutes or regulations. For example, as discussed below, proposed § 92.3 (Scope of application) will define the scope of "health program or activity." Proposed § 92.3 also effectively defines "covered entities" similar to the Final Rule by clarifying that

the rule applies to: (1) every health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided or made available by the Department; (2) any program or activity administered by the Department under Title I of the PPACA; or (3) any program or activity administered by any entity established under such Title. Furthermore, consistent with the text of Section 1557, proposed §§ 92.2 and 92.3 provide that “Federal financial assistance” includes credits, subsidies, or contracts of insurance.

The proposed rule uses the same characteristics as are included in the definitions of “qualified interpreter” for an LEP individual and of “qualified translator” in describing the requirements that an interpreter and translator, respectively, should meet (but omits the word “qualified” which is implied by the context). *See* proposed § 92.101(b)(3)(i) and (ii). The proposed rule also retains nearly verbatim, as requirements with respect to the provision of language access services, the characteristics used to define “language assistance services.” *See* proposed § 92.101(b)(2).

Additionally, the proposed rule retains most of the disability-rights related definitions from the current rule either explicitly, such as the definitions of “disability” and “information and communication technology;” by using the definition to describing the requirements or characteristics of the entity, such as when describing a “qualified interpreter” for an individual with a disability; or by referencing underlying regulations or statutes, such as for technical accessibility standards and definitions.

In other cases, some terms are clear enough to obviate the need for further definition given the context of the proposed rule including terms such as “age,” “individual with limited English proficiency,” “qualified bilingual/multilingual staff,” or “individual with a disability.” In these examples, OCR will continue to interpret the phrases naturally and consistent with the Final Rule.

The Department will also continue to abide by terms defined in the definitions sections of the implementing regulations for the underlying statutes. In fact, the Department believes it is generally more appropriate to rely on individual definitions applicable to individual statutes incorporated into Section 1557 as opposed to picking one standard (or creating a new one) and making it applicable in all cases, as under the Final Rule.

The Department asks for comment on whether other definitions should be included in the regulatory text.

Redesignation Table	
Old Section	New Section
92.201(g)	92.101(c)
92.202	92.102
92.203	92.103
92.204	92.104
92.205	92.105

The remaining provisions of Section 1557 would be repealed. A description of each proposed provision of the Section 1557 Regulation follows:

Proposed “Subpart A—General Provisions”

Proposed “45 CFR 92.1 Purpose.”

This proposed section describes the purpose of the proposed regulation as providing for the enforcement of Section 1557, which prohibits discrimination

under any health program or activity receiving Federal financial assistance, or under any program or activity administered by an Executive agency under Title I of the PPACA or by any entity established under such Title, on the grounds of race, color, national origin, sex, age, or disability. The proposed section would provide that the Department's Office for Civil Rights (OCR) enforces these prohibitions using the mechanisms set forth in the Department's Title VI, Title IX, Age Act, and Section 504 regulations. The proposed section would replace the current § 92.1 in its entirety.

Proposed "45 CFR 92.2 Nondiscrimination requirements."

This proposed section describes the core substantive requirements of compliance with Section 1557 under the proposed regulation. Namely, the Department proposes to provide that, except as otherwise provided by Title I of the PPACA, an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department, or under any program or activity administered by the Department under such Title, or under any program or activity administered by any entity established under such Title, on any grounds prohibited under the following statutes:

(1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (race, color, national origin);

(2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (sex);

- (3) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) (age); or
- (4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (disability).

The cross-reference to existing civil rights statutes does not change the prohibited grounds of discrimination, but applies them, to the extent they did not already apply, to the health care context. Thus, for example, the cross-referencing of Title IX (which prohibits sex discrimination in education programs or activities) in Section 1557 and in the proposed regulation means that sex discrimination, as defined by Title IX, is prohibited in health programs or activities to which this proposed part applies, not merely health programs or activities related to education. This proposed section would replace current § 92.2 in its entirety.

In keeping with the text of Section 1557, proposed § 92.2 would apply to health programs or activities receiving Federal financial assistance, “including credits, subsidies, or contracts of insurance.”

Although Section 1557 prohibits discrimination by any program “administered by an Executive Agency,” the Final Rule itself acknowledged the difficulty of the Department enforcing the rule with respect to programs administered by other agencies.⁹³ Many other agencies have their own rules implementing the underlying statutes incorporated in section 1557. *See, e.g.* 65 FR 52857 (Title IX common rule for 21 Federal agencies). HHS, therefore, proposes to continue the general limitation on the rule’s scope found in the Final Rule, specifically, that the proposed rule not assert or encompass enforcement

⁹³ In the preamble to the Final Rule, the Department acknowledged its limited ability to regulate programs covered by other agencies. 81 FR 31379 (“Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges”).

jurisdiction over entities receiving Federal financial assistance administered by another agency under Section 1557.

The current regulation, however, departed from this general principle by defining Federal financial assistance to include assistance that HHS “does not have primary responsibility for administering,” but merely “plays a role” in providing or administering. 81 FR 31384; 45 CFR 92.4. This gloss goes beyond the text of Section 1557, which, in relevant part, only covers certain programs or activities “administered” by the Department, not any program in which the Department “plays a role in administering.” In keeping with the text of Section 1557, the proposed regulation would not retain the “plays a role” language. As a result, the proposed rule would no longer cover issuers of Exchange plans solely on the basis that HHS plays a role in administering tax credits, also administered by the Internal Revenue Service.⁹⁴ Exchange plans, however, may still be subject to antidiscrimination enforcement by the Department under Section 1557 on other grounds, or under other antidiscrimination authorities. For example, qualified health plans (QHPs) sold on the Exchanges established under Title I of the PPACA are subject to Section 1557, and the issuers of QHPs are subject to regulation by the Department’s Center for Consumer Information and Insurance Oversight, of the Centers for Medicare & Medicaid Services.

⁹⁴ In the preamble to the Final Rule, the Department acknowledged its limited ability to regulate programs covered by other agencies. 81 FR 31379 (“Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges”). Additionally, the Department has not applied the Final Rule to the risk adjustments program (Section 1343 of the PPACA), and does not propose to do so in this proposed rule. *See also* 45 CFR 153.310 (risk adjustment administration).

The Department seeks specific comment on the proposed elimination of the “plays a role” language.

The Final Rule applies to “every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.” 45 CFR 92.2. But Section 1557, with respect to the administration of programs by the Department and PPACA’s Title I entities, does not include the term “health.” Rather Section 1557 applies to “any program or activity” administered by the Department or any entity established under Title I of the PPACA.

The Department added the health limitation to the current rule because it did not believe Section 1557 was intended to apply to every program or activity administered by every Executive agency whether or not it had any relation to health. Accordingly, the preamble to the Final Rule stated it covered health programs administered by CMS, HRSA, CDC, Indian Health Service (IHS), and SAMHSA (for example, IHS tribal hospitals and clinics operated by the Department and the National Health Service Corps) but not any human services programs administered by the Department. 81 FR 31446. The Department continues to believe that Congress did not provide such expansive coverage, but believes that Section 1557 itself already provides a meaningful limitation without resort to inserting the word “health” when Congress did not do so, Section 1557 specifies that it applies to any program or activity administered by the Department (or other Executive Agency) “under this title,” meaning Title I of the PPACA. To be consistent with the text as passed by Congress, the proposed § 92.2 would apply to any program or activity administered by the Department under Title I of the PPACA and

any program or activity administered by any entity established under such Title. Entities established under Title I of the PPACA include the health insurance exchanges established pursuant to the PPACA. Such exchanges currently include the 12 State Exchanges, 5 State Exchanges on the Federal platform, and 34 Federally-facilitated Exchanges. Title I additionally establishes, among other things, State advisory councils concerning community health insurance (section 1323).

The Department seeks public comment on the impact of this language, including on mechanisms for identifying affordable health insurance coverage options (Sec. 1103), the wellness program demonstration project (Sec. 1201, adding Public Health Service (PHS) Act Section 2705(l)), and the provision of community health insurance options (Sec. 1323).

Proposed “45 CFR 92.3 Scope of application.”

This proposed section would clarify that the scope of application of the proposed rule would be consistent with the Civil Rights Restoration Act (CRRRA), which defined the scope of the underlying civil rights laws based on whether or not an entity receiving Federal financial assistance is or is not principally engaged in the business of providing health care.

Proposed § 92.3 clarifies the scope of entities covered by the rule by specifying that the rule applies to: (1) any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department; (2) any program or activity administered by the Department under Title I of the PPACA; or (3) any program or activity administered by any entity established under such Title. Furthermore, as

provided in Section 1557 of the PPACA⁹⁵ and in proposed § 92.2, the Department interprets “Federal financial assistance” in the proposed rule to apply to credits, subsidies, or contracts of insurance.

With respect to entities receiving Federal financial assistance, the current regulation defines the operation of a “health program or activity” to cover “all [] operations” of such entities when they are principally engaged in providing or administering “health services or health insurance coverage or other health coverage.” 45 CFR 92.4. The CRRRA, however, defined “program or activity” under Title VI, the Rehabilitation Act, the Age Act, and Title IX to cover all the operations of entities only when they are “principally engaged in the business of providing education, *health care*, housing, social services, or parks and recreation.” Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (emphasis added).

“Health insurance” is distinct from “health care.” *Compare* 5 U.S.C. 5371 (“‘health care’” means direct patient-care services or services incident to direct patient-care services”) *with* 42 U.S.C. 300gg-91 (“The term ‘health insurance coverage’ means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.”).⁹⁶ The Final Rule,

⁹⁵ 42 U.S.C. 18116(a) (Section 1557 applies to recipients of Federal financial assistance for contracts of insurance).

⁹⁶ *See also* 45 CFR 160.103 (HIPAA administrative simplification) (“*Health care* means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the

however, went beyond the CRRA by covering all the operations of entities that are principally engaged in providing “health insurance coverage or other health coverage,” even if they are not principally engaged in the business of providing “health care,” despite there being nothing in Section 1557 indicating any abrogation – or extension – of the CRRA.⁹⁷

Therefore, to provide further clarity on these issues and return to the CRRA’s statutory text, proposed § 92.3 would explicitly incorporate the CRRA standard. The Department also believes this approach is an appropriate interpretation of the phrase “health program or activity.” If an entity is principally engaged in the business of health care, the Department proposes to interpret Section 1557 so that all operations of that entity would be deemed part of any “program or activity” it engages in, any part of which receives Federal financial assistance. If, on the other hand, an entity is not principally engaged in the business of health care, the Department proposes to interpret Section 1557 so that only the operation for which it receives Federal financial assistance is part of the “program or activity.”

Specifically, the proposed section would set forth the general applicability standard from Section 1557: that it applies to any health program or activity, any part of which is receiving Federal financial assistance administered by the Department, including credits, subsidies, or contracts of insurance, or under any

following: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.”).

⁹⁷ The preamble to the Final Rule acknowledges the relevance of the CRRA, 81 FR at 31386, but does not explain how the provision of “health care” covers the provision of “health insurance, even if only part of the health program or activity receives such assistance.”

program or activity that is administered by the Department or any entity established under Title I of the PPACA.

Further, the Department proposes that § 92.3 provide that the regulation would cover all of the operations of any entity that receives Federal financial assistance from the Department and that is principally engaged in the business of providing health care, as part of a “health program or activity.” For any entity not principally engaged in the business of providing health care, “health program or activity” under the proposed regulation would apply to such entity’s operations only to the extent any such operations receive Federal financial assistance.

Finally, the proposed section would clarify that, for purposes of the rule, an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing health care.

The proposed regulation would not apply to entities that do not receive Federal financial assistance from the Department. Likewise, as discussed above concerning the CRRA, the Department proposes that where entities receive Federal financial assistance but are not principally engaged in the business of providing health care, the regulation would not apply to the components or activities of those entities that do not receive Federal financial assistance. If an entity, such as a health insurance issuer, receives Federal financial assistance from the Department to further a health program or activity but is not principally engaged in the business of providing health care, the proposed regulation would apply to the entity’s specific operations which receive Federal financial assistance from the Department, but it

would not apply to the entity’s entire operations.⁹⁸ Thus, for example, the proposed rule would generally not apply to short term limited duration insurance (STLDI) because, as the Department understands it, providers of STLDI are either (1) not principally engaged in the business of health care, or (2) not receiving Federal financial assistance with respect to STLDI plans specifically.⁹⁹

Under the proposed section, examples of entities principally engaged in the business of providing health care would include hospitals, nursing facilities, hospices, community health centers, and physical therapists. Examples of recipients of Federal financial assistance from the Department for health programs or activities would include laboratories, medical schools, and nursing schools. Examples of recipients of Department assistance for contracts of insurance would include Medicare Part C (Medicare Advantage).

The proposed rule would not apply to Medicare Part B (except to the extent participation in a health care program is required for engaging in other operations),¹⁰⁰ or self-funded group health plans under the Employee Retirement Income Security Act of 1974 (ERISA), Federal Employees Health Benefits (FEHB) Program, or STLDI plans because (or to the extent) such programs do not receive

⁹⁸ Compare with *Grove City College v. Bell*, 465 U.S. 555(1984) (holding that receipt of Federal financial aid does not automatically trigger institution-wide coverage under Title IX) *abrogated in part by* the CRRRA.

⁹⁹ The Public Health Service Act expressly excludes STLDI from its definition of “individual health coverage,” and the PPACA does not deem short term limited duration insurance to be qualifying coverage under the PPACA’s minimum essential coverage requirements. 42 U.S.C. 300gg–91(b)(5); 26 U.S.C. 5000A; *see also* 83 FR 38212 (Aug. 3, 2018) (rule clarifying definition of short-term, limited-duration insurance to Departments of Treasury, Labor, and Health and Human Services regulations at 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103).

¹⁰⁰ The Department believes that the Federal financial assistance does not include Medicare Part B under the Social Security Act. *See* 2 CFR 200.40(c) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for Federal Awards); 45 CFR 75.502(h) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for HHS Awards).

Federal financial assistance from HHS and/or the entities operating them are not principally engaged in the business of providing health care as discussed above.

The Department seeks public comment on issues related to the scope of coverage under the proposed rule, including whether it should define “health care” in the rule according to the statutes cited above defining the term, 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.

Proposed “45 CFR 92.4 Assurances.”

The Department contemplates retaining current § 92.5, requiring covered entities to submit an assurance of compliance with Section 1557 to the Department without change, but proposes to redesignate it as § 92.4. Paragraph (a) requires applicants for the Department’s Federal financial assistance for health programs or activities, health insurance issuers seeking certification to participate in an Exchange, and States seeking approval to operate State Exchanges to submit assurances that the health program or activity will comply with Section 1557 and its regulation. Paragraph (b) clarifies that assurances of compliance with Section 1557 apply to the period during which Federal financial assistance is extended, or the applicable property is used, owned or possessed. Paragraph (c) requires that assurances with Section 1557 must be contained in covenants running with applicable property, interest, and land transfers from the Department. The source of these provisions is the Department’s Section 504 regulations, and while Section 504

regulations have more detail, they do not have major substantive requirements that differ from their Title IX, Title VI, or Age Act regulations.¹⁰¹

The Department proposes to retain the assurance provisions and identify “Section 1557” on a consolidated assurance form with Title VI, Title IX, Section 504, and the Age Act to include major applicable civil rights laws and require all applicable covered entities to submit the assurance. The Department believes keeping Section 1557 on a consolidated form ensures that the insurance industry and States are aware that these Federal civil rights laws currently apply to them.

The Department seeks comment on whether it is appropriate to retain the requirement to submit an assurance of compliance with Section 1557 to the Department, or whether it unnecessarily duplicates requirements in the underlying regulations to provide such assurances of compliance to the Department.

Proposed “45 CFR 92.5 Enforcement mechanisms.”

This proposed section would ensure that even under the proposed rule’s repeal of certain provisions of the Section 1557 Regulation, the enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, and the Department’s implementing regulations, shall apply for purposes of enforcement of Section 1557. Other than as proposed in the conforming amendments discussed in Part IV, the proposed rule would not repeal or otherwise amend the regulations implementing

¹⁰¹ Compare 45 CFR 84.5 (Section 504) with 45 CFR 86.4 (Title IX), 80.4(a) (Title VI), 91.33 (Age Act).

and enforcing Title VI at 45 CFR parts 80 and 81, Title IX at 45 CFR Part 86, Section 504 at 45 CFR parts 84 and 85, and the Age Act at 45 CFR parts 90 and 91.

The proposed § 92.5 also designates the Director of the Department's Office for Civil Rights to receive complaints, conduct compliance reviews, and otherwise investigate and take enforcement actions with respect to allegations of discrimination in violation of Section 1557 under this part.¹⁰²

Proposed “45 CFR 92.6 Relationship to other laws.”

The Department proposes § 92.6, to define the relationship of the regulation to other laws with more specificity than the current sections titled “Application” (§ 92.2) and “Relationship to other laws” (§ 92.3). The Department proposes to combine the substance of these two sections into a new § 92.6. It would set forth the text of Section 1557(b) nearly verbatim, and state that nothing in the proposed regulation shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, or to displace additional protections under State antidiscrimination laws.

The proposed section would also specify that the proposed regulation not be applied in a manner that conflicts with or supersedes exemptions, rights, or

¹⁰² The Office of Personnel Management (OPM) handles of claims alleging discrimination in the Federal Employees Health Benefits (FEHB) Program. OPM is charged by Federal statute with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards.

protections contained in several civil rights statutes, including those just mentioned, the Architectural Barriers Act of 1968,¹⁰³ the Americans with Disabilities Act of 1990 (as amended by the Americans with Disabilities Act Amendments Act of 2008),¹⁰⁴ Section 508 of the Rehabilitation Act of 1973,¹⁰⁵ and statutes protecting conscience and religious freedom.

Although the Section 1557 Regulation incorporated exemptions to Title VI, Section 504, and the Age Act,¹⁰⁶ it did not incorporate abortion,¹⁰⁷ religious,¹⁰⁸ and other¹⁰⁹ exemptions contained in Title IX. The Final Rule considered the question of explicitly incorporating the Title IX religious exemption in the Section 1557 Regulation, but declined, instead providing that, “[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.”

The *Franciscan Alliance* court stated that the Department’s failure to incorporate statutory exemptions “nullifies Congress’s specific direction to prohibit

¹⁰³ 42 U.S.C. 4151 *et seq.*

¹⁰⁴ 42 U.S.C. 12181 *et seq.*

¹⁰⁵ 29 U.S.C. 794d.

¹⁰⁶ See 45 CFR 92.101(c) (The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17–.18 of this Subchapter.”)

¹⁰⁷ “Nothing in this title shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities related to an abortion....” Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (codified at 20 U.S.C. 1688).

¹⁰⁸ 20 U.S.C. 1681(a)(3) (providing that the prohibition of discrimination on the basis of sex “shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization”); *see also* 45 CFR 86.12 (Title IX exemption for educational organizations controlled by religious organizations). 81 FR 31435 (HHS declines to include a religious exemption in Section 1557).

¹⁰⁹ 20 U.S.C. 1681(a)(6)(B) (Title IX exemption for voluntary youth service organizations); 1686 (separate living facilities); 45 CFR 86.33 (exemption for separate toilet, locker room, and shower facilities).

only the ground proscribed by Title IX.” *Franciscan Alliance*, 227 F. Supp. 3d at 690-691 (citations omitted). The *Franciscan Alliance* court held that there was a likelihood that plaintiffs would prevail on the claim that “[t]he Rule’s failure to include Title IX’s religious exemptions renders the Rule contrary to law.”¹¹⁰

In its April 5, 2019, brief in *Franciscan Alliance*, DOJ, on behalf of HHS, stated that the prohibition on sex discrimination under Section 1557 “unambiguously includes Title IX’s exemptions, including those addressing religion and abortion.”¹¹¹ This statement represents the Department’s own further consideration of this issue, guided by DOJ’s pronouncements on Title VII and Title IX. The Department believes that its enforcement of Title IX, and its enforcement of Section 1557 (to the extent it incorporates Title IX), must be constrained by the statutory contours of Title IX, which include explicit abortion and religious exemptions and which should be set forth more clearly than in the Final Rule.¹¹²

In the Department’s view, Section 1557 did not override any statutes protecting conscience or civil rights, and the exemptions thereto, and it is appropriate to specify that the Section 1557 Regulation will not be implemented in violation of those laws. Indeed, Section 1303 of the PPACA states that nothing in the PPACA shall be construed to require qualified health plans to cover abortions as an essential health benefit (42 U.S.C. 18023(b)(1)(A)(i)) and “[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience

¹¹⁰ 227 F. Supp. 3d at 690-91.

¹¹¹ See Defendant’s Memorandum in Response to Plaintiffs’ Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-O, p. 11 (N.D. Tex, filed April 5, 2019).

¹¹² As discussed further below, HHS also proposes to amend its underlying Title IX regulation to include the statutory abortion and religious exemptions explicitly.

protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or provide or participate in training to provide abortion” (42 U.S.C. 18023(c)(2)(A)). With respect to Section 1303 of the PPACA, this language is contained in a provision labeled “NO EFFECT ON FEDERAL LAWS REGARDING ABORTION” and is in a section that dealing with “special rules” about abortion. However, the language (“conscience protections”) is not limited to abortion.

In light of the PPACA’s text and structure and the experience of the *Franciscan Alliance* litigation, the proposed section would incorporate by reference statutory exemptions and protections concerning religious and abortion exemptions with greater clarity than the Final Rule’s § 92.2(b)(2) which currently states that, “[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.”

This current provision would be amended and replaced by the proposed § 92.6 which provides that, “[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the[se] statutes [] . . . or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.”

Additionally proposed § 92.6 would explicitly identify and incorporate protections from specific religious freedom, conscience, and nondiscrimination statutes—42 U.S.C. 18113 (Section 1553 of the Patient Protection and Affordable

Care Act); 42 U.S.C. 2000bb *et seq.* (the Religious Freedom Restoration Act, which applies to “all Federal law . . . unless such law explicitly excludes such application”); 42 U.S.C. 238n (the Coats-Snowe Amendment); 42 U.S.C. 300a-7 (the Church Amendments); the Weldon Amendment (*e.g.*, Consolidated Appropriations Act of 2019, Pub. L. 115-245, Div. B, sec. 506(d) (Sept. 28, 2018)); and related conscience provisions in appropriations law (*e.g.*, Consolidated Appropriations Act of 2019, Pub. L. 115-245, Div. B, sec. 506) (Sept. 28, 2018)).

Proposed “Subpart B—Specific Applications”

Proposed “45 CFR 92.101 Meaningful access for individuals with limited English proficiency.”

The Department proposes to redesignate § 92.201, on providing meaningful access for individuals with limited English proficiency (LEP), as § 92.101 and, as so redesignated, to amend the provision to more closely align with the Department’s 2003 LEP guidance.

In proposed paragraph (a), the Department sets forth the governing standard for the provision of meaningful access to programs and activities receiving Federal financial assistance based on the U.S. Supreme Court decision of *Lau v. Nichols*, 414 U.S. 563 (1974), which interprets Title VI’s prohibition of discrimination on the basis of “national origin” in the context of LEP individuals. Subsection (a) also incorporates language from the Department of Justice’s and HHS’s LEP guidance documents. *See* 67 FR 41455 (June 18, 2002) (DOJ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons); 68 FR 47311 (Aug. 8,

2003) (HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

Proposed paragraph (a) would adopt the standard from DOJ's and HHS's LEP guidance by specifying that any entity operating or administering a health program or activity subject to this rule shall take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals. Because Section 1557 applies to a broader scope of entities than only recipients of federal financial assistance, the Department proposes to use "entity" rather than "recipient" which retains the nomenclature used in the current rule with respect to LEP access.

Adopting this language would apply the same standard to both health and human services within the Department, and conform to the other Federal agencies who follow DOJ's LEP guidance, consistent with its civil rights coordinating authority. This standard is also consistent with Department's LEP guidance.¹¹³ This provision is proposed to replace the current rule's provision which requires that reasonable steps to provide meaningful access be provided to each LEP individual eligible to be served or likely to be encountered.¹¹⁴

¹¹³ 68 FR 47312 (Aug. 8, 2003) (HHS LEP guidance) (stating that "Title VI and its implementing regulations require that recipients take reasonable steps to ensure meaningful access by LEP persons." See also 67 FR 41455 (June 18, 2002) (DOJ LEP Guidance); Executive Order 13166 on Improving Access to Services for Persons with Limited English Proficiency, 65 FR 50121 (Aug. 16, 2000) (directing all Federal agencies to develop LEP guidance consistent with DOJ's LEP guidance).
¹¹⁴ 45 CFR 92.201(a). But see 68 FR 47312, 47314 (Aug. 8, 2003) (HHS LEP guidance) (stating that recipients may conclude that "in certain circumstances" recipient-provided language services are not necessary).

Proposed paragraph (b) would likewise adopt the four factors from the Department’s existing LEP guidance to assist entities in determining the extent of a covered entity’s obligation to provide language assistance services. The Department proposes to clarify that the starting point for OCR’s exercise of its enforcement discretion would be an individualized case-by-case assessment that balances the following four factors: (1) the number or proportion of LEP individuals eligible to be served or likely to be encountered in the eligible service population; (2) the frequency with which LEP individuals come in contact with the entity’s health program, activity, or service; (3) the nature and importance of the entity’s health program, activity, or service; and (4) the resources available to the entity and costs. 68 FR at 47314-15 (HHS guidance); *accord* 67 FR at 41459-60 (factors from DOJ’s 2002 LEP guidance).¹¹⁵ By using the factors as written in the Department’s LEP Guidance, the proposed rule would use the same factors in health care that already apply to all of the Department’s programs, including human services.

Although the current Section 1557 Regulation states that it applies to individuals “eligible to be served or likely to be encountered,”¹¹⁶ it did not explicitly address factors such as the number or proportion of LEP individuals, the frequency of contact, the resources available, or the costs identified in the Department’s LEP

¹¹⁵ The Department notes that, in both its LEP guidance and in the Department of Justice’s LEP guidance, language in factor (1) also refers to LEP persons rather than individuals, refers to the number of those persons served or encountered rather than those eligible to be served or likely to be encountered, and refers to those served or encountered by the program or grantee rather than in the eligible service population. . Likewise, language in factor (3) refers to the nature and importance of the program, activity, or service provided by the program to people’s lives. The Department believes that these variations in descriptions of the factors have the same meaning, but asks for comment on which formulation of these factors it should use for purposes of this rulemaking.

¹¹⁶ 45 CFR 92.201(a).

guidance.¹¹⁷ Additionally the Final Rule newly required the OCR Director to take into account whether a covered entity had developed and implemented an effective written language access plan in evaluating compliance.¹¹⁸ By contrast, the HHS LEP Guidance had stated that “[r]ecipients with very few LEP persons and recipients with very limited resources, may choose not to develop a written LEP plan.” 68 FR 47320. The Department also stated in its guidance that recipients have “alternative and reasonable ways to articulate” how they are providing meaningful access to LEP individuals besides through written language access plans. *Id.*

Because of these departures from the Department’s LEP guidance, the Department anticipated that 50% of covered entities would develop language access plans subsequent to the finalization of the Section 1557 Regulation, amounting to a total annualized cost of \$84.1 million over five years (undiscounted). 81 FR 31459.

The Department seeks comment on this proposed provision with respect to how health care providers would articulate their responsibilities under the proposed rule and comment on any related costs or cost savings.

Next, the Department retains § 92.201(c) through (e) and (g) from the current rule, but proposes to redesignate these provisions as § 92.101(b)(2) through (4) and (c), with the proposed clarifying revision that these obligations, which are applicable to specific language services, would apply only to the extent necessary to comply with the standard articulated in (a) (which is consistent with the HHS LEP guidance), as informed by the entity’s individualized assessment of the

¹¹⁷ *But see* 45 CFR 92.201(b) (including a catchall allowing the Director to “take into account other relevant factors”).

¹¹⁸ *See* 45 CFR 92.201(a).

four factors. In general, language assistance services, if required to be offered by an entity, must be no-cost, timely, and accurate. If the standard requires an entity to offer translators or interpreters, they must also meet specific minimum qualifications, including ethical principles, confidentiality, proficiency, effective interpretation, and ability to use specialized terminology as necessary in the health care setting. The proposed paragraph also provides a list of other types of “language assistance services” to mirror the definition of the phrase under the current rule, with the exception of taglines, which the Department no longer believes constitute the actual provision of a service, as opposed to the notification of the availability of services.

Like the current rule, when interpretation services are required by the rule, the proposed rule would prohibit an entity from requiring a LEP individual to bring his or her own interpreter or rely on a minor child or accompanying adult to facilitate communication, except under limited exceptions.

Finally, the Department proposes to redesignate § 92.201(f), which identified specific technical and training requirements for use of video remote interpreting services for LEP individuals, as § 92.101(b)(3)(iii), and, as so designated, to revise the provision. In § 92.201(f), the Department extended the application of the Americans with Disabilities Act regulatory definition of “video remote interpreting services” which requires video that is high quality, real-time, full-motion large, sharply delineated, and that does not transmit blurry or grainy images. *See* 45 CFR 35.160. Although individuals with hearing impairments rely on accurately seeing sign language interpreters (and the proposed rule retains these access standards for

persons who are deaf or hard of hearing), foreign language speakers can, in many circumstances, rely solely on a clear audio transmission for effective communication. Given that equipment and training costs for more sophisticated video remote interpreting technology can be more expensive than audio,¹¹⁹ the Department believes that additional video standards may not justify the costs, particularly with respect to small providers.¹²⁰

The Department seeks comment on the extent to which covered entities rely on video remote interpreting for LEP individuals, circumstances where a clear video signal (as opposed to audio) would be necessary for effective communication, the applicable costs of this service, and whether such standards improve the effectiveness of communication. Consequently the Department proposes to repeal certain provisions on video standards for remote language interpretation services, but retain the audio standards which require clear, audible transmission of voices, use of quality video connection without lagging or irregular pauses in transmission, and applicable training of staff to use the remote interpreting technology.

¹¹⁹See Barb Jacobs, Anne M. Ryan, *et al.*, *Medical Interpreters in Outpatient Practice*, 16:1 *Annals of Family Medicine* 70-76 (Jan. 2018), <https://doi.org/10.1370/afm.2154> (stating that costs can be “considerable,” ranging from \$1.25 to \$3.00 per minute for audio interpreters, and \$1.95 to 3.49 per minute for video interpreters, sometimes with minimum number of minutes required per session. Setup costs for video remote interpreting equipment vary, depending on whether a laptop, desktop, or cameras, speakers and microphones are used”).

¹²⁰ Christopher M. Burkle, Kathleen A. Anderson, *et al.*, *Assessment of the efficiency of language interpreter services in a busy surgical and procedural practice*, *BMC Health Services Research* 17:456 (2017), <https://doi.10.1186/s12913-017-2425-7> (“With increasing numbers of LEP patients over time along with any new mandates for providing language assistance, the financial implications for many health care facilities will likely continue to be a challenge”).

Finally, paragraph (c), by retaining the provision currently found at § 42.201(g), would clarify that Section 1557 does not require patients to accept the language access services offered by a provider.

In its proposed revisions to its meaningful access requirements, the Department attempts, in accordance with Supreme Court guidance, to strike an appropriate balance with respect to the Title VI rights of LEP individuals and the burdens imposed on the regulated community. The Department believes that its proposal – in what it proposes to retain, and in what it proposes to revise – strikes the right balance and provides benefits greater than the burdens imposed. The Department nevertheless seeks comment on whether it has struck that proper balance with respect to benefits and burdens.

The Department seeks comment particularly in light of the proposed retention of some provisions that impose requirements on covered entities under the Section 1557 Regulation (which govern health programs or activities) but not on entities who only receive HHS funding for human services. Specifically, on whether there is or will continue to be problems, confusion or further complexity in implementing the regulations arising from differing standards, and if so, what could or should be done to address such problems/issues, including the possibility of amending the Department’s Title VI regulation.

The Department retains several key definitions with respect to LEP services. The proposed rule incorporates, as requirements with respect to interpreters and translators, the elements of the definitions of “qualified interpreter” for an individual with LEP and of “qualified translator” in the text of the rule. *See* proposed

§ 92.101(b)(3). In other cases, some terms are clear enough so as to not require a definition, such as “individual with limited English proficiency.” In this example, OCR will continue to interpret the phrase as under the Final Rule to mean “an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.” Similarly, OCR will continue to interpret the phrase “qualified bilingual/multilingual staff” to mean a member of a covered entity’s workforce who is designated by the covered entity to provide oral language assistance as part of the individual’s current, assigned job responsibilities and who has demonstrated to the covered entity that he or she: (1) Is proficient in speaking and understanding at least spoken English and the spoken language in need of interpretation, including any necessary specialized vocabulary, terminology and phraseology, and (2) is able to effectively, accurately, and impartially communicate directly with LEP individuals in their primary languages.

The Department contemplates also continuing to abide by terms defined in the definition section of the Title VI regulation where relevant to LEP issues.

Proposed “45 CFR 92.102 Effective communication for individuals with disabilities.”

The Department retains § 92.202 of the current rule, but proposes to redesignate it as § 92.102. Paragraph (a) requires that communications with individuals with disabilities must include provision of appropriate auxiliary aids and services, bars requiring that individuals with disabilities bring their own interpreters, sets minimum standards for video remote interpreting and telephone relay services, exempts covered entities from actions that result in a fundamental

alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, and requires appropriate timeliness, respect for privacy concerns, and independence of the individual with a disability. Paragraph (b) requires recipients of Federal financial assistance and State Exchanges subject to part 92 to provide appropriate auxiliary aids. These provisions are drawn from regulations implementing Title II of the Americans with Disabilities Act, which applies to any public entity,¹²¹ and which were promulgated by the Department of Justice. *See* 28 CFR 35.160 through 35.164.

As stated earlier, although the Department proposes to repeal the definitions section, it would still apply many of the definitions that the Section 1557 Regulation incorporated from the Americans with Disabilities Act (“ADA”) (42 U.S.C. 12101 *et seq.*) or its regulations. The definitions incorporated from the ADA are the following: disability,¹²² auxiliary aids and services,¹²³ qualified interpreter,¹²⁴ video remote interpreting,¹²⁵ information and communications technology,¹²⁶ technical

¹²¹ “Public entity” includes State or local government; any department, agency, special purpose district, or other instrumentality of a State or States or local government. 42 U.S.C. 12311; *see also* 28 CFR 35.104(3). The proposed rule instead uses “entity” with respect to provisions concerning disability rights, as it does with other provisions concerning who or what is covered by the proposed rule.

¹²² 42 U.S.C. 12102 (The term “disability” means with respect to an individual—(A) a physical or mental impairment that substantially limits one or more major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment.” 42 U.S.C. 12102(1)).

¹²³ The list of auxiliary aids and services from 28 CFR 35.104 is incorporated into the proposed rule at § 92.102(b)(1).

¹²⁴ The description of a qualified interpreter from 28 CFR 35.104 informs the description in the proposed rule at § 92.101(b)(3).

¹²⁵ The description of video remote interpreting at 28 CFR 36.303(f) is incorporated by reference in the proposed rule at § 92.102(b)(1)(i).

¹²⁶ 36 CFR part 1194, appendix D, D1194.4.

definitions and standards under the ADA,¹²⁷ and Uniform Federal Accessibility Standards as promulgated.¹²⁸ The Department also proposes to retain the Current Rule's definitions of "oral transliterators"¹²⁹ and "cued language transliterators."¹³⁰

The Department seeks comment on whether to propose an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees. The Department's current Section 504 regulations permit the exemption, but allow the OCR Director discretion to impose a requirement on recipients with fewer than 15 employees if provision of auxiliary aids and services would not significantly impair the ability of the recipient to provide the benefits or services. *See* 45 CFR 84.52(d). The OCR Director announced such a requirement in 2000. *See* Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000). The Final Rule did not include the exemption because the Department believed that imposing the requirement on all entities would promote "uniformity and consistent administration of law." 81 FR 31407.

Proposed "45 CFR 92.103 Accessibility standards for buildings and facilities."

The Department proposes to retain § 92.203 of the current rule, but to redesignate it as § 92.103. Subsection (a) requires that new construction or alteration of buildings or facilities subject to Section 1557 must comply with the

¹²⁷ Appendix D to 28 CFR part 36 and 28 CFR 35.104.

¹²⁸ 49 FR 31528 (Aug. 7, 1984), <https://www.access-board.gov/guidelines-and-standards/buildings-and-sites/about-the-aba-standards/ufas>.

¹²⁹ The Section 1557 Rule defined "oral transliterators" as "individuals who represent or spell in the characters of another alphabet". 45 CFR 92.4.

¹³⁰ "Cued language interpreters" are defined as "individuals who represent or spell by using a small number of handshapes"). 45 CFR 92.4.

2010 ADA Standards for Accessible Design by January 18, 2018. However, this paragraph allows departures from the 2010 ADA standards where other methods are permitted that provide substantially equivalent or greater access to and usability of the building. Subsection (b) contains a safe harbor for new construction or alteration of buildings or facilities subject to Section 1557, allowing existing facilities which were only required to be compliant with the UFAS standards, 1991 ADA Standards, or the 2010 ADA Standards as of July 18, 2016, to be deemed compliant, unless there is new construction or alteration after January 18, 2018. The source of these provisions, Title III of the Americans with Disabilities Act, applies to any public or private owner, lessor, or operator of a place of public accommodation,¹³¹ any public or private owner, lessor, or operator of commercial facilities,¹³² or private entities that offer examinations or courses related to applications, licensing, certification, or credentialing for secondary or postsecondary education, professional, or trade purposes.¹³³

The Department seeks comment on the appropriateness of applying the 2010 ADA Standards' definition of "public building or facility" to all entities covered under Section 1557, specifically with respect to benefits to individuals and disabilities or burdens on private entities related to multistory building elevator¹³⁴ and TTY¹³⁵ requirements.

¹³¹ 42 U.S.C. 12812(a). *See also* 28 CFR 35.102 (DOJ regulations apply to "all services, programs, and activities provided or made available by public entities").

¹³² 42 U.S.C. 12183.

¹³³ 28 CFR 36.102(a)(3).

¹³⁴ Exception 1 of section 206.2.3 of the 2010 Standards exempts multistory buildings besides the professional office of a health care provider owned by private entities from the requirement to provide an elevator to facilitate an accessible route throughout the building. This exemption does

Proposed “45 CFR 92.104 Accessibility of information and communication technology for individuals with disabilities.”

The Department retains § 92.204 of the current rule, but proposes to redesignate it as § 92.104. Paragraph (a) requires covered entities to ensure that their health programs or activities provided through information and communication technology are accessible to individuals with disabilities, except when resulting in an undue financial or administrative burden or fundamental alteration in the nature of an entity’s health program or activity. Paragraph (b) requires effective communication over Federally-facilitated Exchange websites and Department administered health programs or activities it administers.

The Department proposes to use the term “information and communication technology” as defined in the Architectural and Transportation Barriers Compliance Board (“U.S. Access Board”) regulations implementing Section 508 of the Rehabilitation Act (36 CFR part 1194, appendix A, E103.4). In the Final Rule, HHS stated that it would use the terminology and its definition from the U.S. Access Board regulations. 81 FR 31382. At the time of the Final Rule’s promulgation, the Architectural and Transportation Barriers Compliance Board regulations had been proposed but the rulemaking process had not concluded. The proposed Section 1557 rule includes the updated citation and nomenclature change from the now

not apply to public entities.

¹³⁵ The 2010 ADA Standards also specifies TTY requirements for public buildings different from private buildings. *Compare* ADA 2010 Standard 217.4.3.1 (public buildings) *with* ADA 2010 Standard 217.4.3.2 (private buildings).

finalized U.S. Access Board regulation. 82 FR 5790 (Jan. 18, 2017) (Final Rule); 83 FR 2912 (Jan. 22, 2018) (technical edits).

Paragraph (b) states the requirements of Section 504 as applied to the Department and Department-conducted or administered health programs or activities. *See* 29 U.S.C. 794 (Section 504); 45 CFR Part 85 (Section 504). However, in addition to Section 504, Section 508 of the Rehabilitation Act and its implementing regulations also apply to each Federal department or agency. *See* 29 U.S.C. 794d; *see also* 45 CFR Part 85 (Section 504), 36 CFR 1194.1 and Apps. A, C, and D.¹³⁶ The Department seeks comment as to whether the Department should cross-reference Section 508 and its applicable implementing regulations in proposed § 92.104.

Proposed “45 CFR 92.105 Requirement to make reasonable modifications.”

The Department retains § 92.205 of the current rule, but proposes to redesignate it as § 92.105. This section requires covered entities to make reasonable modifications to policies, practices, or procedures when necessary, to avoid discrimination on the basis of disability, except if the modification would fundamentally alter the nature of the health program or activity. This provision is derived from regulations implementing Title II of the Americans with Disabilities Act promulgated by the Department of Justice and imposed on all public entities. *See* 28 CFR 35.104.

¹³⁶ When conformance to requirements in the Revised 508 Standards would impose an undue burden or would result in a fundamental alteration in the nature of the ICT, conformance is required only to the extent that it does not impose an undue burden or result in a fundamental alteration in the nature of the ICT. The Section 1557 Regulation does not override the standards under Section 508 that concurrently apply to the Department and Department-conducted health programs or activities.

The Department seeks comment whether this provision should be retained or substituted with language conforming to the Department of Justice’s Section 504 coordinating regulations which state that covered entities “shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified” individual with a disability. *See* 28 CFR 92.205. The Department also seeks comment whether to include an exemption for “undue hardship.” *See* 45 CFR 84.12 (HHS Section 504 regulation); 28 CFR 92.205 (DOJ Section 504 coordinating regulation).

Request for Comments on Proposed 45 CFR 92.102 through 92.105

In retaining the requirements imposed in the Section 1557 Regulation through Section 504 with respect to disability, the Department seeks to strike an appropriate balance with respect to the Section 504 rights of individuals with disabilities and the obligations imposed on the regulated community. With respect to the requirement for regulated entities to provide assurances, the Department also seeks to strike an appropriate balance. The Department believes that, in retaining all of these requirements, it has struck that balance and provides benefits greater than the burdens it imposes. Even so, the Department seeks comment on whether it has struck that proper balance by retaining the provisions, and whether the benefits of these provisions exceed the burdens imposed by them. The Department also seeks comment on whether, in light of the proposed retention of such provisions, the requirements imposed on covered entities under the 1557 regulations differ from those entities who are only subject to the underlying civil rights laws and regulations (*e.g.*, the Department’s human services grantees), and whether there is

or will continue to be problems, confusion or further complexity in implementing the regulations arising from any lack of consistency of the requirements imposed under the regulations and, if so, what could or should be done to address such problems or issues.

The Department seeks comment on whether revisions should be made to these provisions and whether they are adequately addressed in the underlying regulations (or should be) or if additional cross references should be made.

B. Current Section 1557 Regulation Provisions Proposed for Repeal or Reconsideration

The proposed rule would repeal certain provisions of the Section 1557 Regulation that conflict with, or unnecessarily duplicate, the statutory text of Section 1557, Federal case law, the four statutes incorporated by Section 1557 (Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973), or their implementing regulations. The proposal to repeal such provisions from the Section 1557 Regulation would leave in place all of the substantive protections of Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973 and the enforcement mechanisms of those statutes referenced at proposed § 92.2. As discussed above, the Department does not propose to remove several provisions prohibiting discrimination against individuals with disabilities: with respect to effective communication, accessibility of buildings and facilities, accessibility of information and communication technology, and the requirement to

make reasonable modifications. The Department also does not propose to repeal the provision on assurances of compliance with Section 1557. A provision on language access services for LEP individuals is retained (with proposed revisions), with the exception of the provisions on taglines, notices of nondiscrimination, the use of language access plans, and video standards, as described in the following section, as well as many duplicative provisions.

1. Taglines, Notices, Language Access Plans, and Video Interpretation

Standards

The Department proposes to repeal *in toto* the Section 1557 provisions on taglines,¹³⁷ the use of language access plans,¹³⁸ and notices of non-discrimination.¹³⁹ The Department also proposes to replace the requirements for remote English-language video interpreting services with comparably effective requirements with respect to audio-based services.¹⁴⁰ The current rule's provisions were not justified by need, were overly burdensome compared to the benefit provided, and created inconsistent requirements for HHS funded health programs or activities as compared to HHS funded human services programs or activities. The Department proposes to return to the language access standard previously in place under the existing Title VI regulation as interpreted by the U.S. Supreme Court and HHS and the Department of Justice in their LEP guidance documents. Other Department

¹³⁷ See 45 CFR 92.4 (definition of taglines), 92.8(d) (posting of taglines), 92.8(e) (languages of taglines), 92.8(f) (tagline notices), 92.8(g) (taglines in significant publications and communications); Appendix B to 45 CFR Part 92 (sample tagline).

¹³⁸ 45 CFR 92.201(b)(2) (requiring the OCR Director to "take into account...whether a covered entity has developed and implemented an effective written language access plan, that is appropriate to its particular circumstances" in evaluation of compliance). 45 CFR 92.201(b)(2).

¹³⁹ 45 CFR 92.8; Appendix B to 45 CFR Part 92 (sample notice).

¹⁴⁰ 45 CFR 92.201(f).

regulations that require the provision of taglines in certain healthcare contexts¹⁴¹ and do not otherwise track, reference, or rely on Section 1557 or its regulations would not be impacted by the proposed repeal of the taglines provisions.¹⁴²

When it promulgated the Section 1557 Regulation, the Department did not discuss all available Department data on the extent of voluntary compliance with HHS's LEP 2003 guidance. In 2010, the Department's Office of the Inspector General (OIG) published two reports,¹⁴³ which found that the vast majority of Medicare providers and plans in counties with high proportions of LEP persons surveyed in

¹⁴¹ *E.g.*, 42 U.S.C. 300gg-15(b)(2) and 300gg-19(a)(1)(B) (requiring standards for ensuring that the Summaries of Benefits and Coverage and certain notices are provided in a culturally and linguistically appropriate manner); 42 U.S.C. 1396d(p)(5)(A) (requiring HHS to distribute to States an application form for Medicare cost-sharing in English and 10 non-English languages); 26 CFR 1.501(r)-4(a)(1), (b)(5)(ii) (requiring a hospital organization to translate certain documents, among other requirements, to qualify for a tax-exempt status with respect to a hospital facility); 42 CFR 422.2262(a)(1)-(2) and 422.2264(e) (setting forth Medicare Advantage marketing requirements, which include requiring Medicare Advantage organizations to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area), 423.2262(a)(1)-(2) and 423.2264(e) (setting forth Medicare Part D marketing requirements, which include requiring Part D plan sponsors to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area); 45 CFR 155.205(c)(2)(iii)(A) (Marketplaces must post taglines on their websites and include taglines in documents "critical for obtaining health insurance coverage or access to health care services through a QHP"); 45 CFR 147.136(e)(2)(iii) and (e)(3), and 147.200(a)(5) (requiring taglines in languages in which 10% of individuals with limited English proficiency (LEP) county-wide are exclusively literate on internal claims and appeals notices and on an issuer's Summary of Benefits and Coverage); 42 CFR 435.905(b)(3) (requiring individuals to be "informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services"); 42 CFR 457.340(a) (applying certain Medicaid requirements, including 435.905(b)(3), which requires individuals to be "informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services"); 210 Illinois Cons. Stat. 87/1 (Illinois Language Assistance Act).

¹⁴² *See, e.g.*, 45 CFR 155.205(c)(2)(iii)(A) (deeming compliance with the LEP provisions of the Section 1557 regulation to constitute compliance with CMS's LEP requirements).

¹⁴³ HHS OIG, Guidance and Standards on Language Access Services: Medicare Providers (July 2010) (OIG Providers Report), <https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf> (surveying 140 randomly selected Medicare providers, such as hospitals and nursing homes, that directly supply health care services to beneficiaries); HHS OIG, Guidance and Standards on Language Access Services: Medicare Plans (July 2010) (OIG Plans Report), <https://oig.hhs.gov/oei/reports/oei-05-10-00050.pdf> (surveying 139 randomly selected private companies that contract with CMS to provide health insurance under Medicare Advantage or prescription drug coverage under Medicare Part D).

2009 conducted the assessment recommended in HHS's guidance.¹⁴⁴ Additionally, in that 2010 report, 27% of providers cited the cost of offering language services as an obstacle.¹⁴⁵ The generally high rate of voluntary action is one reason that the Department proposes to repeal some of the Final Rule's LEP mandates and replace them with the principles and factors of HHS's LEP guidance. The Department requests comment on these OIG reports, and requests other surveys or reports, if available, with more current or comprehensive data, to evaluate the level of voluntary compliance with the best practices identified in the Department's LEP guidance.

2. Redundant Provisions Duplicative of Pre-Existing Regulations

The Section 1557 Regulation contains provisions that are duplicative of, inconsistent with, or may be confusing in relation to the Department's pre-existing Title VI, Section 504, Title IX, and the Age Act regulations. In some cases, they may also be duplicative of, inconsistent with, or confusing in relation to coordinating regulations published by DOJ for Title VI and Section 504, applicable to recipients of Federal financial assistance. *See* 28 CFR Parts 41 (Section 504) and 42 (Title VI).

These Section 1557 provisions relate to definitions;¹⁴⁶ health insurance coverage;¹⁴⁷ certain employee health benefits programs;¹⁴⁸ notification of rights of

¹⁴⁴ OIG Providers Report at 34; OIG Plans Report at 29.

¹⁴⁵ OIG Providers Report at 23.

¹⁴⁶ Compare 45 CFR 92.4 (Section 1557) with 45 CFR 80.13 (Title VI), 85.3 (Section 504), 86.2 (Title IX) and 91.12 (Age Act).

¹⁴⁷ Compare 45 CFR 92.207 (non-discrimination in health-related insurance and other health-related coverage under Section 1557) with 45 CFR 80.5 (health benefits under Title VI), 84.43 (health insurance under Section 504), 84.52 (health benefits under Section 504), 84.33 (rule of construction of Section 504 vis-à-vis validly obligated payments from health insurer); 86.39 (health insurance benefits and services under Title IX).

beneficiaries under civil rights laws;¹⁴⁹ designation of responsible employees and adoption of grievance procedures;¹⁵⁰ access granted to OCR for review of covered entities' records of compliance;¹⁵¹ prohibitions on intimidation and retaliation;¹⁵² and remedial action and voluntary action.¹⁵³

The Department seeks comment on the provisions proposed for repeal, and which of these, if any, should be preserved, in whole or part, in the rule, whether they are already addressed in the underlying regulations (or should be), and with particular comments requested about the following subjects:

- Coverage of certain employee health benefit programs.
- Designation of responsible employees and adoption of grievance procedures.
- Notification of beneficiaries, enrollees, applicants, patients, and/or members of the public of rights and responsibilities under civil rights laws.

IV. Need for Conforming Amendments

In conjunction with the proposed new provisions for the Section 1557 regulation, the Department proposes to add provisions containing Title IX's

¹⁴⁸ Compare 45 CFR 92.208 (employer liability for discrimination in employee health benefit programs in Section 1557) with 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX). In view of the current 1557 rulemaking, the enforcement Memorandum of Understanding (MOU) between OPM and the Department, available at <https://www.hhs.gov/sites/default/files/opm.pdf>, would be moot if this proposed rule were to become final. Moreover, because the MOU is akin to subregulatory guidance, it is suspended during this rulemaking, consistent with Section V below.

¹⁴⁹ Compare 45 CFR 92.8 and Appendix A to 45 CFR Part 92 (Section 1557) with 45 CFR 80.6 and Appendix to Part 80 (Title VI), 84.8 (Section 504), 86.9 (Title IX) and 91.32 (Age Act).

¹⁵⁰ Compare 45 CFR 92.7 and Appendix C to 45 CFR Part 92 (Section 1557) with 45 CFR 84.7 (Section 504), and 86.8 (Title IX).

¹⁵¹ Compare 45 CFR 92.303(c) (Section 1557) with 45 CFR 91.31 (Age Act) and 80.6(c) (Title VI).

¹⁵² Compare 45 CFR 92.303(d) (Section 1557) with 45 CFR 80.7(e) (Title VI) and 91.45 (Age Act).

¹⁵³ Compare 45 CFR 92.6 (Section 1557) with 45 CFR 84.6 (Section 504), 86.3 (Title IX), and 91.48 (Age Act).

exemptions to its Title IX Regulation in order to conform it to the statute, be consistent with the Section 1557 regulation, and reflect current law. This proposed rule would also amend regulations governing certain HHS-funded or HHS-administered health programs covered by Section 1557 or Title IX in order to conform them to the scope of the changes defined by this proposed rule.

A. Nondiscrimination in Education Programs or Activities

In conjunction with the proposed Section 1557 Regulation, the Department proposes to conform the Title IX regulation to statutory exemptions consistent with the Section 1557 regulation and current law. Although the Section 1557 Regulation incorporated exemptions of Title VI, Section 504, and the Age Act,¹⁵⁴ it did not incorporate the abortion and religious exemptions contained in Title IX. The *Franciscan Alliance* court stated that the Department's failure to incorporate statutory exemptions "nullifies Congress's specific direction to prohibit only the ground proscribed by Title IX." *Franciscan Alliance*, 227 F. Supp. 3d at 690-691 (citations omitted).

In its April 5, 2019 brief in *Franciscan Alliance*, DOJ, on behalf of HHS, stated that the prohibition on sex discrimination under Section 1557 "unambiguously includes Title IX's exemptions, including those addressing religion and abortion."¹⁵⁵ To address the *Franciscan Alliance* court's holding and ensure a consistent and

¹⁵⁴ See 45 CFR 92.101(a)(6) (The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17-.18 of this Subchapter.)

¹⁵⁵ See Defendant's Memorandum in Response to Plaintiffs' Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-O, p. 11 (N.D. Tex, filed April 5, 2019).

equitable enforcement approach, HHS proposes to amend its Title IX regulation to include the statutory abortion¹⁵⁶ and religious¹⁵⁷ exemptions.

The Final Rule did not include an affirmative religious exemption in the Section 1557 Regulation, but stated that “Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.” The *Franciscan Alliance* court held that there was a likelihood that plaintiffs would prevail on the claim that “[t]he Rule's failure to include Title IX's religious exemptions renders the Rule contrary to law.”¹⁵⁸ After further consideration of this issue, the Department concludes that any enforcement of Title IX by the Department, and, therefore, any enforcement of Section 1557 to the extent it incorporates Title IX, must be constrained by the statutory contours of Title IX, which include its abortion and religious exemptions, and must be set forth more clearly than occurred in the Final Rule. Therefore, to comply with the *Franciscan Alliance* court's decision and Congress's directives in Title IX and Section 1557, and to properly give effect to religious liberty and conscience protections related to the provision of abortion services provided explicitly under Title IX, the Department proposes to amend its Title IX regulation to conform to the statute.

¹⁵⁶ “Nothing in this title shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities related to an abortion....” Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (codified at 20 U.S.C. 1688).

¹⁵⁷ 20 U.S.C. 1681(a)(3) (providing that the prohibition of discrimination on the basis of sex “shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization”); 81 FR 31435 (HHS declines to include a religious exemption in Section 1557).

¹⁵⁸ 227 F. Supp. 3d at 690-671.

In the Final Rule, the Department stated that termination of pregnancy¹⁵⁹ was included as a prohibited basis of discrimination on the basis of sex under the Section 1557 Regulation in order to “mirror” the text of the Department’s Title IX regulation. 81 FR at 31387 (May 19, 2016) (Section 1557 Final Rule); *see also* 80 FR at 54176 (Sept. 8, 2015) (Section 1557 Proposed Rule). However, the Department did not incorporate relevant abortion exemption language from the text of Title IX itself. 20 U.S.C. 1688.¹⁶⁰ As the *Franciscan Alliance* court noted:

Title IX prohibits discrimination on the basis of sex, but . . . categorically exempts any application that would require a covered entity to provide abortion or abortion-related services. 20 U.S.C. § 1688. . . . Failure to incorporate Title IX’s religious and abortion exemptions nullifies Congress’s specific direction to prohibit only the ground proscribed by Title IX. That is not permitted.

Franciscan Alliance, 227 F. Supp. 3d at 690-91.

Proposed “45 CFR 86.18 Amendments to conform to statutory exemptions.”

To resolve the current litigation, avoid future litigation over the Department’s Title IX and Section 1557 regulations, and give effect to the statutory abortion exemption provisions adopted by Congress and relevant rules of

¹⁵⁹ Although this proposed rule does not adopt a position on whether discrimination on the basis of termination of pregnancy can constitute discrimination on the basis of sex, it does not mean that OCR could not consider such claims of discrimination, such as discrimination on the basis of miscarriage or discrimination on the basis of medical complications resulting from a termination of pregnancy.

¹⁶⁰ The Civil Rights Restoration Act (CRRA) added the following language to Title IX, “Nothing in this chapter shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.” Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (codified at 20 U.S.C. 1688). The CRRA also included a rule of construction stating that “No provision of this Act or any amendment made by this Act shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion.” *Id.* at Sec. 8.

construction adopted by Congress, the Department proposes to amend its Title IX regulations at 45 CFR part 86 to add a new Section 86.18.

In proposed § 86.18(a), the Department seeks to codify the abortion exemption to Title IX. The Department proposes to use the text Congress added to Title IX by means of the CRRRA – which states that “Nothing in this chapter shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion,” Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (codified at 20 U.S.C. 1688) – as the basis of the regulatory text, making the appropriate changes to reflect the difference between the statute and the implementing regulations.

Proposed § 86.18(b) would set forth the rule of construction in Title IX, as added by the CRRRA. The Department again proposes to base the regulatory text on the language of the rule of construction adopted by Congress: “No provision of this Act or any amendment made by this Act shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion.” *Id.* at Sec. 8.

In proposed § 86.18(c), the Department proposes to incorporate other relevant laws that may impact the application of the Title IX abortion exemption. This paragraph would incorporate the laws cited by the *Franciscan Alliance* court: the Religious Freedom Restoration Act,¹⁶¹ the Weldon Amendment,¹⁶² the Coats-

¹⁶¹ 42 U.S.C. 2000bb-1.

¹⁶² *E.g.*, Pub. L. 114–113, Div. H, sec. 507(d), 129 Stat. 2242, 2649 (2015).

Snowe Amendment,¹⁶³ and the Church Amendments.¹⁶⁴ See 227 F. Supp. 3d at 690-91. The Department also proposes to reference the First Amendment to the U.S. Constitution, the Hyde Amendment,¹⁶⁵ the Helms Amendment,¹⁶⁶ and Section 1303 of the Patient Protection and Affordable Care Act.¹⁶⁷ The Department concludes that all of these statutes establish Congressionally required parameters that may apply to the Department’s interpretation, implementation, and enforcement of Title IX.¹⁶⁸

The Department requests comment on proposed § 86.18.

B. Proposed Conforming Amendments

The Department proposes to amend certain regulations that identify “sexual orientation” or “gender identity” as prohibited bases of discrimination for certain Department health programs or activities, to the extent that the regulations are not based on independent statutory authority which expressly provides such prohibition. As stated above, Congress through Section 1557 adopted certain nondiscrimination requirements for health programs or activities, any part of which receive Federal financial assistance or programs or activities administered by an Executive agency under Title I of the PPACA or by an entity established under such Title by cross-referencing the grounds for discrimination prohibited by longstanding civil rights laws—namely, race, color, national origin, sex, age, or

¹⁶³ 42 U.S.C. 238n.

¹⁶⁴ 42 U.S.C. 300a-7.

¹⁶⁵ *E.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, sec. 506(a).

¹⁶⁶ *E.g.*, Continuing Appropriations Act, 2019, Pub. L. 115–245, Div. C, sec. 7018.

¹⁶⁷ 42 U.S.C. 18023.

¹⁶⁸ To the extent the law is found in an appropriations rider, it applies to the Department’s interpretation, implementation, and enforcement of Title IX every year that it is enacted.

disability. Neither Section 1557 nor any of those longstanding civil rights laws reference sexual orientation or gender identity.

Moreover, as noted in the preamble to the Final Rule, the current regulation does *not* treat “an individual’s sexual orientation status alone [a]s a form of sex discrimination under Section 1557,” 81 FR 31390. It is the position of the United States government that Title VII, which is read consistent with or carries over to Title IX when determining the scope of discrimination on the basis of “sex,” “does not reach discrimination based on sexual orientation.” DOJ Brief for the United States as *Amicus Curiae*, *Zarda v. Altitude Express, Inc.*, No. 15-3775 (2d Cir. July 26, 2017). It is also the position of the United States government that “Title VII’s prohibition on sex discrimination . . . does not encompass discrimination based on gender identity *per se*, including transgender status.” Memorandum of the Attorney General (Oct. 4, 2017).¹⁶⁹ As discussed above, on April 5, 2019, DOJ filed a brief in *Franciscan Alliance v. Azar* on behalf of HHS, reiterating the U.S. Government’s position about Title VII, and stating that “the [Section 1557] Rule’s prohibitions of discrimination on the basis of gender identity and, without the accompanying statutory protections, termination of pregnancy are substantively unlawful under the APA.”¹⁷⁰

This proposed rule, thus, seeks to amend regulations that identify sexual orientation or gender identity as prohibited bases for discrimination for certain

¹⁶⁹ Memorandum of the Attorney General, (Oct. 4, 2017), <https://www.justice.gov/ag/page/file/1006981/download>.

¹⁷⁰ See Defendant’s Memorandum in Response to Plaintiffs’ Motions for Summary Judgment, *Franciscan Alliance*, No. 7:16-cv-00108-0, at 5 (filed April 5, 2019).

Department funded or administered programs covered by Section 1557 in order to conform them more closely to the prohibited bases for discrimination authorized by Section 1557, and encompassed in the proposed § 92.2, and to conform them with government policy. The provisions proposed to be conformed are:

- 45 CFR 155.120(c)(1)(ii) and 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.

- 45 CFR 147.104(e), nondiscrimination provision concerning marketing or benefit design practices of health insurance issuers under the PPACA.

- 45 CFR 156.200(e) and 156.1230(b)(3), nondiscrimination provision concerning the administration of qualified health plans (QHP) by issuers and concerning marketing and other conduct by QHP issuers engaged in direct enrollment of applicants under the PPACA.

- 42 CFR 460.98(b)(3) and 460.112(a), nondiscrimination provisions concerning organizations operating Programs for All-inclusive Care of the Elderly (PACE) programs and participants receiving PACE services under Medicare.

- 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262, nondiscrimination provisions concerning Medicaid beneficiary enrollment, and promotion and delivery of access and services.

Additionally, the Department proposes to amend its Title IX regulation at 45 CFR 86.31 to remove any potential ambiguity or conflict concerning the current regulation's prohibition of discrimination "in the application of any rules of

appearance.” Currently, the Department is the only Federal agency with Title IX regulatory language prohibiting discrimination “against any person in the application of any rules of appearance.”¹⁷¹ 45 CFR 86.31(b)(5) (retained from the predecessor 1975 HEW regulation). While “rules of appearance” does not appear in Title IX and was never defined in any agency’s Title IX regulations, the phrase may cause confusion in the public about Title IX’s coverage and compliance responsibilities and has already led to at least one lawsuit.¹⁷² Because this language is not in current regulations of any other agencies, the proposed edit would eliminate the potential for conflicting and inequitable Federal agency enforcement of Title IX. *See Jespersen v. Harrah’s Operating Co.*, No. 03-15045 (9th Cir. Apr. 14, 2006) (en banc) (finding sex-specific uniform, appearance and grooming standards did not violate Title VII’s prohibition on sex discrimination).

C. Technical Amendments

Several technical amendments are proposed to the Department’s Section 1557 and Title IX regulations. The Department makes a nomenclature change to replace “State-based MarketplaceSM” with “State Exchange” to conform the proposed rule to CMS regulations. *See* 45 CFR 155.20. The Department also makes a

¹⁷¹ *See, e.g.*, 47 FR 32527 (July 28, 1982) (Department of Education Title IX regulation); 65 FR 52858 (Aug. 30, 2000) (common rule adopted by twenty agencies), 66 FR 4627 (Feb. 20, 2001) (common rule adopted by Department of Energy); 82 FR 46656 (Oct. 6, 2017) (U.S. Department of Agriculture adopting common rule). None of these agency Title IX rules contain any language concerning “rules of appearance.”

¹⁷² *See* Complaint, *Peltier et al. v. Charter Day School*, No. 7:16-CV-30-H, No. 160 (E.D.N.C. Mar. 30, 2017) (citing “rules of appearance” in Department of Agriculture’s Title IX regulation to challenge a school’s girls’ dress code for “subject[ing] them to archaic sex stereotypes about what constitutes appropriate behavior and conduct”); *but see* 82 FR 46655 (Oct. 6, 2017) (by adopting the Title IX common rule, the Department of Agriculture no longer contains language about “rules of appearance”).

nomenclature change from “electronic and information technology” to “information and communication technology”¹⁷³ and updates the regulatory cross-reference in this definition from the Access Board’s former 508 Standards (36 CFR 1194.4) to its revised 508 Standards (36 CFR part 1194, appendix A, E103.4). The Department also inserts cross-references to ADA 2010 Standards, 1991 Standards, and UFAS in the regulatory text concerning accessibility for individuals with disabilities.

The Department proposes to make a conforming amendment to § 86.2, which defines Title IX for purposes of the regulation as certain enumerated provisions in the U.S. Code. When the Department updated its Title IX regulation in 2005 in order to conform to the 1987 CRRA, the Department failed to add all relevant statutory citations, including 20 U.S.C. 1688, which requires neutrality with respect to abortion. *Compare* 70 FR 24314 (May 9, 2005) *with* Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988) (CRRA). The Department’s Title IX regulation should encompass all relevant provisions of the statute it is regulating and, accordingly, the Department proposes to edit § 86.2 include references to 20 U.S.C. 1687 and 1688 to correct the omission.

The enforcement section in the Department’s Title IX regulation currently only addresses applicable procedures for the interim period between Title IX’s “effective date and the final issuance of a consolidated procedural regulation applicable to Title IX and other civil rights authorities.” 45 CFR 86.71. The proposed

¹⁷³ Although the Section 1557 Regulation uses the term “electronic and information technology” (EIT) in § 92.204, the Department stated that it would update its nomenclature to the U.S. Access Board’s then-proposed new term “information and communication technology” (ICT) upon finalization of the U.S. Access Board regulation. 81 FR 31382 (Section 1557 Final Rule). *See also* 82 FR 5790 (Jan. 18, 2017) (Access Board ICT Final Rule).

rule would address current enforcement procedures by adopting the same language from the Title IX common rule, which incorporates Title VI procedures.

The proposed rule would also make nomenclature change to the Title IX regulation by replacing “United States Commissioner of Education” with the official’s current title, “Secretary of Education.” *See* 45 CFR 86.2(n).

V. Interim Treatment of Subregulatory Guidance

Because the enforcement mechanisms of the underlying four civil rights statutes in Section 1557 are already enshrined in the Department’s free standing regulations, and implemented and enforced by the Department’s Office for Civil Rights, existing sub-regulatory guidance not inconsistent with this rulemaking would not be impacted by this rulemaking. Other subregulatory guidance may, however, be inconsistent with the Department’s interpretation of Section 1557 and Title IX, and its requirement to comply with court orders.

Upon publication of this notice of proposed rulemaking, the Department will, as a matter of enforcement discretion, suspend all subregulatory guidance issued before this proposed rule that interprets or implements Section 1557 (including FAQs,¹⁷⁴ letters,¹⁷⁵ and the preamble to the current Section 1557 Regulation) that is

¹⁷⁴ After publishing the Final Rule, OCR issued guidance explaining that anything printed on an 8.5” x 11” sheet of paper is considered “significant,” and, thus, must include the tagline notice. *See* OCR, Question 23, General Questions about Section 1557 (May 18, 2017), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html>; *see also* OCR, Sample Covered Entity Tagline Informing Individual with Limited English Proficiency of Language Assistance, <https://cms-drupal-hhs-prod.cloud.hhs.gov/sites/default/files/sample-ce-tagline-english.pdf>. This documents are examples of sub-regulatory guidance that must be suspended under this proposed rule. *See also* OCR, Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement, <https://cms-drupal-hhs-prod.cloud.hhs.gov/sites/default/files/sample-ce-notice-english.pdf>; OCR, Frequently Asked Questions to Accompany the Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency under Section 1557 of the Affordable Care

inconsistent with any provision in this proposed rule (including the preamble) or with the requirements of the underlying civil rights statutes cross-referenced by Section 1557 or their implementing regulations. This suspension may be revoked wholly or partially at any time before finalization of this proposed rule and will be lifted automatically if this proposed rule is withdrawn. This suspension is consistent with the Attorney General's memorandum of November 16, 2017, stating that, for the Department of Justice, "guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch. Nor should guidance create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements."¹⁷⁶ It is also consistent with the Associate Attorney General's memorandum of Jan. 25, 2018, indicating that Department of Justice litigators cannot use noncompliance with guidance documents as the basis for proving violations of law in affirmative civil enforcement cases and may not use its enforcement authority to convert agency guidance documents into binding rules.¹⁷⁷

VI. Regulatory Impact Analysis

The Department has examined the impacts of the proposed rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (Oct. 4,

Act, (Sept. 1, 2016), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/top15-languages/index.html>.

¹⁷⁵ On July 12, 2012, the OCR Director first announced in a correspondence addressed to a single member of the public that OCR was accepting and investigating complaints of discrimination on the basis of "actual or perceived sexual orientation or gender identity" under Section 1557 of the PPACA. OCR Transaction Number 12-00800 (July 12, 2012).

¹⁷⁶ Memorandum of the Attorney General, "Prohibition on Improper Guidance Documents." <https://www.justice.gov/opa/press-release/file/1012271/download>.

¹⁷⁷ Memorandum of the Associate Attorney General, "Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases." <https://www.justice.gov/file/1028756/download>.

1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (Aug. 4, 1999); Executive Order 13175 on Tribal Consultation, 65 FR 67249 (Nov. 6, 2000); Executive Order 13771 on Reducing Regulation and Controlling Costs, 82 FR 9339 (Jan. 30, 2017); the Congressional Review Act (Pub. L. 104-121, sec. 251, 110 Stat. 847 (Mar. 29, 1996)); the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, 109 Stat. 48 (Mar. 22, 1995); the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164 (Sept. 19, 1980)); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (Aug. 16, 2002); Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, 45 FR 72995 (Nov. 2, 1980), and the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

A. Executive Orders 12866 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review as established in, Executive Order 12866.

As discussed below, the Department has estimated that the proposed rule will have an effect on the economy greater than \$100 million in at least one year in fact it will result in greater than \$100 million in savings. Thus, it has been concluded that this proposed rule is economically significant. It has therefore been determined

that this proposed rule is a “significant regulatory action” (albeit of a deregulatory nature) under Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this proposed rule.

1. Summary of the Proposed Rule

Through Section 1557 of the PPACA, Congress applied certain long-standing civil rights nondiscrimination requirements to any health programs or activities that receive Federal financial assistance, and any programs or activities administered by an Executive agency under Title I of the PPACA or by an entity established under such Title. It did so by cross-referencing the discriminatory grounds prohibited by those longstanding civil rights laws, namely, discrimination on the basis of race, color, national origin, sex, age, or disability, in an array of Federally funded and administered programs or activities. To ensure compliance, Congress dictated that “[t]he enforcement mechanisms provided for and available under” such laws “shall apply for purposes of violations of” Section 1557. The proposed rule would, thus, eliminate most of the provisions in the current Section 1557 Regulation and return to the enforcement mechanisms provided for, and available under, those existing statutes and the Department’s implementing regulations. Specifically, the Department proposes to repeal the provisions which interpret Federal law inconsistently with Federal court opinions or impose burdens that unjustifiably exceed anticipated benefits. These include: the Section 1557 Regulation’s inclusion of novel definitions; language access plan provisions; provisions that set forth new requirements for tagline notices, notices of nondiscrimination, and grievance procedures; application of theories and remedies available under a subset of civil

rights laws to all of them, without analysis of whether such theories and remedies were available under all such civil rights laws; and, provisions based on legal theories that were inconsistent with (or, at a minimum, unnecessarily duplicated) provisions of long-standing regulations of the underlying civil rights laws cited in Section 1557. Consistent with this approach to the Section 1557 Regulation, the Department proposes to retain certain language and disability access provisions, as well as the assurance of compliance requirements. The proposed rule empowers the Department to continue its robust enforcement of civil rights laws by additionally making it clear that the substantive protections of Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973, remain in full force and effect.¹⁷⁸ The Department also proposes to make certain conforming changes to regulations across the Department, and to update its underlying Title IX regulation to adopt statutory amendments, in light of the failures noted by the district court in *Franciscan Alliance*.

2. Need for the Proposed Rule

The Department proposes to substantially replace the Section 1557 Regulation, while retaining certain LEP, disability, and assurances of compliance provisions, in order to better comply with the mandates of Congress, relieve

¹⁷⁸ While Section 1557 does not incorporate nondiscrimination provisions by reference to Title VII, it provides that nothing in Title I of the PPACA is to be construed as invalidating or limiting the rights, remedies, procedures, or legal standards available under certain civil rights laws, including Title VII. 42 U.S.C. 18116(b).

approximately \$3.6 billion in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557.

As stated above, the proposed rule is needed in part because two Federal district courts have determined that the Department exceeded its authority in promulgating parts of the regulation and have enjoined or stayed it from applying those parts. By substantially repealing most of the Section 1557 Regulation, the Department would revert to statutory interpretations more consistent with the law and with the United States Government's official position on certain of the underlying civil rights statutes, and ultimately allow the Federal courts, in particular, the U.S. Supreme Court, to resolve any dispute about the proper legal interpretation of such statute and, thus, on Section 1557 of the Affordable Care Act.

Additionally, the Department has determined that the Final Rule is duplicative and confusing, has imposed substantial unanticipated burdens, and that its anticipated and unanticipated burdens are not justified.

The Department initially estimated the costs from the Section 1557 Regulation at over \$942 million across the first five years. 81 FR 31458-31459. This figure, however, underestimated actual five year costs by at least \$2.6 billion, according to the Department's current estimates. Most of this expense is derived from the taglines requirement, which amounts to an annual burden of approximately \$147 million (low-end) to \$1.34 billion dollars (high-end), before accounting for electronic delivery, for an average annual burden of \$0.632 billion per year, and an average five year burden of \$3.16 billion after accounting for electronic delivery, as further described in this Regulatory Impact Analysis. Based

on the Department's re-examination of the burden on regulated entities, the Department has preliminarily determined that the potential public benefits of imposing such requirements are outweighed by the large costs those requirements impose on regulated entities and other parties.

3. Consideration of Regulatory Alternatives

The Department carefully considered several alternatives, including the option of not pursuing any regulatory changes, but rejected that approach for several reasons.

First, not pursuing any regulatory changes would be inconsistent with the Administration's policies to appropriately reduce regulatory burden, in general, with respect to individuals, businesses and others, and resulting from PPACA specifically. Not pursuing any regulatory change would also be inconsistent with a nationwide preliminary injunction in place against the Department with respect to the inclusion, in the Section 1557 Regulation, of gender identity and termination of pregnancy in the definition of discrimination on the basis of sex.

Second, Federal courts have reached varying conclusions concerning a number of legal positions taken by the Department in the Section 1557 Regulation. The Northern District of Illinois dismissed a plaintiff's claim that the Department created a new enforcement legal standard, because the "plain and unambiguous" statutory text of Section 1557 expressly incorporated four distinct enforcement mechanisms. *Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) (dismissing a Section 1557 claim for sex discrimination using a disparate impact standard); *but see Rumble v. Fairview Health Servs.*, No. 14-cv-2037

(SRN/FLN) (D.Minn. Mar. 16, 2017) (declining to determine the specific standard on motion to dismiss, rejecting implication Congress meant to create a “new anti-discrimination framework completely ‘unbound by the jurisdiction of the four referenced statutes,’” but concluding Congress “likely” intended a single standard to avoid “patently absurd consequences”). In addition, Federal courts in California, New York, and Iowa did not recognize disparate impact claims for sex discrimination under Section 1557, because such claims are not cognizable under Title IX. See *Condry v. UnitedHealth Group*, No. 3:17-cf-00183-VC (N.D. Calif. June 27, 2018) (Slip. Op. at 7); *Weinreb v. Xerox Business Services*, 323 F. Supp. 3d 501, 521 (S.D.N.Y. 2018); *York v. Wellmark, Inc.*, No. 4:16-cv-00627-RGE-CFB, Slip. Op. at *30 (S.D. Iowa Sep. 6, 2017). Another court in Pennsylvania indicated that there is no disparate impact claim for discrimination on the basis of race under Section 1557 because such claims are unavailable under Title VI. See *Southeastern Pennsylvania v. Gilead*, 102 F. Supp. 3d 688 (E.D. Pa. 2015); but see *Callum v. CVS Corp.*, 137 F. Supp. 3d 817 (D.S.C. 2015).

Third, the Department believes that the *status quo* would not address, much less remedy, public confusion regarding complainants’ rights, and covered entities’ legal obligations. The Department believes that revisiting the rule will address inconsistencies between the Department’s underlying regulations and with the regulations and actions taken by other components of the Department. As applied to sex discrimination claims, the Department currently employs a definition of discrimination on the basis of sex under Section 1557 and, thus, under Title IX that varies from the practice of other Departments. Moreover, revising the Section 1557

Regulation will allow the Department to resolve current and future complaints of sexual orientation and gender identity discrimination in a manner consistent with other agencies' enforcement efforts under Title IX. If the Department uses interpretations of Title IX that differ from other Departments, and that diverges from the legal interpretation of the U.S. Government, as set forth by DOJ, it would lead to inconsistent outcomes across complainants and covered entities, with the problem being especially acute in cases involving a single covered entity being investigated with respect to the same allegations by multiple Departments that come to different conclusions on effectively the same question.

The Department also considered adding “gender identity” and “sexual orientation” to a definition of “sex” or “on the basis of sex” under Title IX. The Department concluded it is inappropriate to do so at this time, in light of the government position on the meaning of discrimination on the basis of sex under Title VII and cases on which the U.S. Supreme Court has granted petitions for writs of certiorari to resolve similar questions in the context of Title VII. As a policy matter, the Department believes State and local entities are better equipped to address issues of gender dysphoria or sexual orientation and the sometimes competing privacy interests with sensitivity, especially when young children or intimate settings are involved. The Department’s position will not bar covered entities from choosing to grant protections for sexual orientation and gender identity that are not required by, but do not conflict with, any other Federal law.¹⁷⁹

¹⁷⁹ Policies of covered entities that result in unwelcome exposure to, or by, persons of the opposite biological sex where either party may be in a state of undress—such as in changing rooms, shared

The Department has also determined that more complex forms of regulation, such as economic incentives or performance objectives, are neither appropriate nor feasible solutions to the problem to be solved.

The Department also considered simply repealing the Section 1557 Regulation *in toto* and not issuing a replacement regulation. Such an approach would be consistent with the Administration’s goals of reducing the regulatory burden on covered entities and is allowed under Section 1557, since that provision does not require the Department to issue implementing regulations. However, the Department is committed to vigorous enforcement of civil rights and nondiscrimination laws as directed by Congress. Additionally, it believes that certain provisions—such as those addressing the assurance of compliance with Section 1557, effective communication and accessibility for individuals with disabilities, and certain language access services—address applications of civil rights laws without the statutory or legal conflicts or excessive regulatory burdens entailed by other provisions of the current Rule.

The Department considered retaining the provision on visual standards for video remote interpreting services for LEP individuals. However, the burden of requiring covered entities to provide video technology training and utilize expensive software does not appear to be justified based on minimal benefit to

living quarters, showers, or other shared intimate facilities—may trigger hostile environment concerns under Title IX. *United States v. Virginia*, 518 U.S. 515, 550 n.19 (1996) (“Admitting women to [an all-male school] would undoubtedly require alterations necessary to afford members of each sex privacy from the other sex in living arrangements”); *Fortner v. Thomas*, 983 F.2d 1024, 1030 (11th Cir. 1993) (“[M]ost people have a special sense of privacy in their genitals, and involuntary exposure of them in the presence of people of the other sex may be especially demeaning or humiliating.”).

language speakers who can effectively communicate when there is clear audio transmission through the remote interpreting service.

Accordingly, the Department believes it is appropriate to clarify how the Office for Civil Rights would enforce the PPACA's nondiscrimination protections by replacing the Section 1557 Regulation with regulatory provisions (1) explicitly applying the enforcement mechanisms provided under the civil rights statutes and related implementing regulations cited by Section 1557 to the health contexts identified in Section 1557, (2) vesting enforcement authority under Section 1557 with the Director of the Office for Civil Rights, and (3) specifying how Section 1557 enforcement shall interact with existing laws – while retaining certain language and disability access provisions and the assurances provision.

With respect to the requirement that covered entities provide nondiscrimination notices and taglines, the Department considered keeping the requirement but limiting the frequency of required mailings to one per year to each person served by the covered entity. To estimate the cost of this option, the Department adopted the base assumptions described in this Regulatory Impact Analysis regarding the number of covered entities and the average unit cost associated with the low-end and high-end costs of a notice and tagline mailing (materials, postage, and labor).¹⁸⁰ The Department adjusted the volume of mailings based on the average number of individuals served by each covered entity.¹⁸¹ The

¹⁸⁰ The average of the low (\$0.035) and high (\$0.32) unit costs is \$0.18 per notice and tagline mailing.

¹⁸¹ The estimated volume is expected to vary based on covered entity type. For instance, each of the 180 health insurance issuers serve 685,138 individuals on average, based on the number of insured individuals (123 million), which equates to 685,138 mailings per issuer. Each of the 185,649

Department assumed the same covered entity compliance rate for the insurance industry as under this Regulatory Impact Analysis but assumed an increased compliance rate for non-insurers (assuming 30% instead of 10%) to reflect that more entities would likely comply with the requirements if the burden were to be significantly reduced to one mailing per customer/patient per year. Based on this method, the estimated total cost of this alternative is approximately \$63 million per year. Although this option poses a significantly reduced burden, the Department believes the costs under this alternative still outweigh the benefits because such mass multi-language taglines mailings would still be received overwhelmingly by English speakers and because the requirement to issue non-discrimination notices would be largely duplicative of non-discrimination notice requirements that already exist under Section 1557's underlying civil rights regulations.¹⁸²

The Department invites comment on its proposed approach, as well as the other approaches considered by the Department.

4. Considerations for Cost-Effective Design

In this proposed rule, the Department proposes to substantially replace most of the Section 1557 Regulation, so as to significantly reduce the regulatory burden of compliance and to return to the pre-existing understanding of the underlying nondiscrimination obligations imposed by the civil rights laws referenced by Section 1557.

physicians' offices serve 1,703 individuals, based on the average number of individuals (316 million) associated with 990 million physicians visits. On average, each covered entity serves about 3,000 persons per entity, which equates to 3,000 mailings per entity, based on 820 million persons served by 275,002 covered entities.

¹⁸² See 45 CFR 80.6(d) (Title VI), 84.8 (Section 504), 86.9 (Title IX), 91.32 (Age Act).

In the preamble to the Final Rule, the Department observed there were pre-existing requirements under Federal civil rights laws that, “except in the area of sex discrimination,” applied to a large percentage of entities covered by the Final Rule. 81 FR at 31446. Thus, in the Final Rule the Department concluded it did not expect covered entities to undertake additional costs with respect to the prohibitions on discrimination on the basis of race, color, national origin, age, or disability discrimination, “except with respect to the voluntary development of a language access plan.” *Id.*

By proposing to repeal the Section 1557 Regulation’s novel definition of sex discrimination and to eliminate the notices, taglines, visual standards in video remote interpreting services for LEP individuals, language access plans, and duplicative grievance procedures requirements, the proposed rule would also allow covered entities the freedom to order their operations efficiently, flexibly, and in a cost-effective manner.

Accordingly, returning to the familiar pre-existing requirements and eliminating novel requirements not contemplated nor allowed by Section 1557 is a cost-effective way of (1) removing the unjustified burdens imposed by the Section 1557 Regulation; (2) reducing confusion among the public and covered entities; (3) promoting consistent, predictable, and cost-effective enforcement; and (4) creating space for innovation in the provision of compliant services by covered entities (including flexible and innovative language access practices and technology), while faithfully and vigorously enforcing Section 1557’s civil rights protections.

5. Methodology for Cost-Benefit Analysis

For purposes of this Regulatory Impact Analysis (RIA), the proposed rule adopts the list of covered entities and other costs assumptions identified in the 2016 RIA for the Final Rule. The use of assumptions from the 2016 rulemaking in the present RIA, however, does not mean that the Department adopts those assumptions in any respect beyond the purpose of estimating (1) the number of covered entities that would be relieved of burden, and (2) cost relief. For example, the 2016 rulemaking based several cost estimates on an expansive definition of Federal financial assistance, which significantly impacted the number of covered entities currently burdened by the Final Rule; thus, it is appropriate to use that definition for estimating cost relief.¹⁸³ Such use, however, should not be interpreted as an endorsement or acceptance of the definitions for any other purpose. Moreover, the existing definition of Federal financial assistance under the Section 1557 Regulation is proposed to be repealed in this NPRM.

The Department also does not “carry over” every assumption from the 2016 Section 1557 Regulation for this NPRM’s RIA calculation purposes. Most notably, the Department no longer considers its prior estimates of costs imposed due to the current Section 1557 Regulation’s taglines requirement accurate or valid, and provides a more thorough and accurate estimate for purposes of this NPRM.

Cost savings result from the repeal of (1) the provision on the incentive for covered entities to develop language access plans and (2) the provisions on notice

¹⁸³ The Department seeks public comment in particular on one aspect of the Final Rule where there was no estimate of the number of impacted entities: the number of religious organizations that provide health services and receive Federal financial assistance from the Department. The Department seeks public comment to better estimate the impact of the proposed rule on such religious entities, and the impact of any applicable religious exemptions that might change the effect of the proposed rule on those entities.

and taglines. In addition, the Department quantitatively analyzes and monetizes the impact that this proposed rule may have on covered entities' voluntary actions to re-train their employees on, and adopt policies and procedures to implement, the legal requirements of this proposed rule. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of covered entities might take in response to this proposed rule. The Department requests all relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA.

6. Cost-Benefit Analysis

a. Overview

In 2016, the Department estimated \$942 million¹⁸⁴ in costs (over five years) for the Section 1557 Regulation due to impacts on personnel training and familiarization, enforcement, posting of nondiscrimination notices and taglines, and revisions in covered entity policies and procedures. 81 FR 31446, and 31458-31459 (at Table 5). As stated earlier, the Department estimated in its 2016 rulemaking that these costs would arise *primarily* from requirements imposed by the Section 1557 Regulation with which covered entities were not already complying.¹⁸⁵ The Department specifically identified the Final Rule's interpretation of sex

¹⁸⁴ Throughout the regulatory impact analysis in the Section 1557 Regulation, the 2016 estimates used 2014 dollars unless otherwise noted.

¹⁸⁵ 81 FR 31446 ("to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule").

discrimination to cover gender identity and sex stereotyping,¹⁸⁶ and the Final Rule’s consideration of language access plans for compliance purposes, as provisions triggering the imposition of new costs.¹⁸⁷ See 81 FR 31459 – Table 5.

In 2016, the Department estimated that the Final Rule’s nondiscrimination notice requirement would impose approximately \$3.6 million in one-time additional costs on covered entities. 81 FR at 31469. Regarding these requirements, the Department stated: “We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or \$3.6 million.” 81 FR at 31469. Thus, the total notice and tagline cost was estimated at \$7.2 million in the first year and was predicted to go down to zero after year one despite the regulatory requirement for covered entities to provide notices and taglines to beneficiaries, enrollees, and applicants by appending notices and taglines to all “significant publications and significant communications” larger than postcards or small brochures. *Compare* 81 FR 31458 (Table 5), *with* 45 CFR 92.8.

For reasons explained more fully below, the 2016 estimate of \$7.2 million in one-time costs stemming from the notice and taglines requirement was a gross

¹⁸⁶ 81 FR 31455 (“Although a large number of providers may already be subject to State laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new.”).

¹⁸⁷ Although the Final Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director “shall” take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would be induced to develop and implement a language access plan following issuance of the Final Rule. 81 FR 31454.

underestimation, and thus this proposed rule's elimination of those requirements would generate a large economic savings of approximately \$3.6 billion over five years based on the proposed repeal of the notice and taglines provision.

Table 1. Accounting Table of Benefits and Costs of All Proposed Changes (in millions)						
SAVINGS	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Total (undiscounted)	\$807	\$789	\$770	\$751	\$733	\$3,850
Total (3%)	\$696	\$660	\$626	\$593	\$562	\$3,137
Total (7%)	\$575	\$525	\$479	\$437	\$399	\$2,416
COSTS	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Quantified Costs						
Total (undiscounted)	\$276	0	0	0	0	\$276
Total (3%)	\$238	0	0	0	0	\$238
Total (7%)	\$197	0	0	0	0	\$197
NET TOTAL (undiscounted)						\$3,574
Non quantified benefits and costs are described below						

b. Generally Applicable Tangible and Intangible Benefits and Burdens

The proposed rule would result in other tangible benefits for covered entities. First, because the proposed rule is simple and easily administrable, it would be less likely that covered entities would need to pay for legal advice or otherwise expend organizational resources to understand their obligations under Section 1557, either in general or with respect to any particular situation that arises. Second, the proposed rule would eliminate the need for covered entities to expend labor and money on an ongoing basis to maintain internal procedures for mitigating the legal risk that persists due to unresolved controversy over the meaning of

Section 1557. The Department solicits comment regarding the nature and magnitude of such ongoing costs incurred by covered entities.

The proposed rule would also carry intangible benefits, most important of which is that covered entities would enjoy increased freedom to adapt their Section 1557 compliance programs to most efficiently address their particular needs, benefiting both covered entities and individuals. The value of knowledge of civil rights is difficult to quantify. Covered entities would be free under the proposed rule to implement policies and procedures that comply with Federal civil rights laws in creative, effective, and efficient ways that are tailored to the covered entities and the communities that they serve.

The Section 1557 Regulation likely induced many covered entities to conform their policies and operations to reflect gender identity as protected classes under Title IX. The Department anticipates that, as a result of the proposed rule, some – but not all – covered entities may revert to the policies and practices they had in place before the agency actions that created confusion regarding Title IX’s definition of discrimination on the basis of sex.¹⁸⁸ Such a reversion may naturally entail amending organizational nondiscrimination policies and training materials, and communicating those changes to employees. The process of voluntarily reverting to previous practices would cost covered entities some time and money. In addition, the Department believes that, under the proposed rule, some covered

¹⁸⁸ Covered entities located in jurisdictions that prohibit sexual orientation and gender identity discrimination under State or local laws likely already have policies, training, or grievance procedures concerning sexual orientation and gender identity and likely would not change their policies under the proposed rule.

entities would no longer incur labor costs pursuant to the Section 1557 Regulation associated with processing grievances related to sex discrimination complaints as they relate to gender identity under Title IX because such claims would not be cognizable under the proposed rule.

The Department, however, is uncertain as to the total number of covered entities that would change their policies and grievance processes to reflect the understanding of sex discrimination set forth in this proposed rule. It anticipates that such changes would be influenced by a number of factors, including applicable State and local laws, along with the covered entities' experiences in implementing the previous definition. Accordingly, the Department, at this time, cannot estimate the number of covered entities that would revert to the previous interpretation of "sex" under their internal policies and operations and the related cost and benefits from such change in behavior. The Department solicits public comments and data on this question.

Consequently, the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits as a consequence of the rule—notwithstanding that nothing in the rule precludes covered entities from continuing such policies voluntarily. The Department seeks comments on this question.

The Department also solicits comments regarding this and other intangible benefits that would be conferred by this proposal.

c. Baseline Assumptions

The following discussion identifies the economic baseline from which the Department measures the expected costs and benefits of the proposed rule. Its baseline includes the cost estimates in the Final Rule, in addition to data it has gathered since the Final Rule was implemented, as described in more detail below.

Key assumptions include the following: (1) the Final Rule triggered significant voluntary activity on the part of covered entities, generating both costs and benefits; (2) covered entities were already complying with civil rights laws and related regulations that were in effect before the Final Rule and, thus, the proposed rule does not impose any new burden by reaffirming the requirements of those laws; (3) the projected costs from the Final Rule for years 1 and 2 have been incurred, and the projected costs from years 3, 4, and 5 have not been incurred; (4) repeal of the Final Rule's notice and taglines requirements would not affect notice or tagline requirements required by Centers for Medicare & Medicaid Services guidance or regulations that do not reference, rely on, or depend upon the taglines requirements of the Final Rule; (5) a relatively small percentage of physicians and hospitals currently append notices and taglines to billing statements sent to patients, while all insurance companies append notices and taglines to their explanations of benefits statements; and (6) covered employers are more likely to train employees who interact with the public than those who do not.

d. Covered Entities

(1) Entities Covered By Section 1557

The Final Rule and the proposed rule replacing Section 1557 apply to any entity that has a health program or activity, any part of which receives Federal

financial assistance from the Department, any program or activity administered by the Department under Title I of the PPACA, or any program or activity administered by an entity established under such Title. Covered entities under the current rule's definition¹⁸⁹ include:

(a) Entities with a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance from the Department

The RIA for the Final Rule stated that the Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs or activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, federally qualified health centers receive Federal financial assistance from CMS by participating in Medicaid programs and may also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely capture entities that receive Federal financial assistance from only one component of the Department. Under the Final Rule, the covered entities consisted of the following:

¹⁸⁹ As noted above, we use the list and number of covered entities and other figures from the 2016 Final Rule's RIA in this RIA for the sake of consistency and convenience, but such use does not mean that we adopt or accept any of the underlying analysis, definitions, or assumptions from the Final Rule's RIA for any other purpose related to this proposed rule.

(i) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).¹⁹⁰

Examples of these entities cited in the 2016 RIA include:

- Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
- Skilled nursing facilities/nursing facilities (facility-based and freestanding)
- Home health agencies
- Physical therapy/speech pathology programs
- End stage renal disease dialysis centers
- Intermediate care facilities for individuals with intellectual disabilities
- Rural health clinics
- Physical therapy—independent practice
- Comprehensive outpatient rehabilitation facilities
- Ambulatory surgical centers
- Hospices
- Organ procurement organizations
- Community mental health centers
- Federally qualified health centers.

(ii) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

¹⁹⁰ CMS, Provider of Service file (June 2014), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/POS2014.html>.

(iii) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).¹⁹¹

(iv) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.¹⁹²

(v) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vi) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vii) Qualified health plan issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Exchanges receiving Federal financial assistance through advance payments of premium tax credits and cost sharing reductions and at least 11 health insurance issuers operating in the State Exchanges).¹⁹³

¹⁹¹ HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, <http://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

¹⁹² HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, <http://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

¹⁹³ Qualified Health Plans Landscape Individual Market Medical (2015), <https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7>.

(viii) Physicians receiving Federal financial assistance through Medicaid payments, “meaningful use” payments, and other sources, but not Medicare Part B payments; Medicare Part B payments to physicians are not Federal financial assistance. The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset “meaningful use” payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the 2016 rulemaking, the Department estimated that the Final Rule likely covers almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. Many physicians participate in more than one Federal, State, and local health program that receives Federal financial assistance, and many practice in several different settings which increases the possibility that they may receive payments constituting Federal financial assistance.

For the sake of consistency and convenience, the Department uses the 2016 RIA estimate of the number of physicians receiving Federal financial assistance. As the 2016 RIA noted, based on 2010 Medicaid Statistical Information System data (the latest available), about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.¹⁹⁴ This figure represents about 69% of licensed physicians in the United States when compared to the 890,000 licensed

¹⁹⁴ John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/medicaid-coverage-and-spending-in-health-reform-national-and-state-by-state-results-for-adults-at-or-below-133-fpl.pdf>. Estimates are based on data from FY 2010 MSIS.

physicians reported in the Area Health Resource File.¹⁹⁵ In addition, physicians receiving Federal payments from non-Part B Medicare sources will also come under Section 1557. The 2016 RIA noted that, as of January 2014, 296,500 Medicare-eligible professionals had applied for funds to support their “meaningful use” technology efforts.¹⁹⁶ Adding the approximately 614,000 physicians who receive Medicaid payments to the 296,500 physicians who receive meaningful use payments yields over 900,000 physicians potentially reached by Section 1557 because they participate in Federal programs other than Part B of Medicare. Because physicians can receive both Medicaid and meaningful use payments, and these figures are not adjusted for duplication, the 900,000 result is best interpreted as an upper bound.

When the Department compared the upper bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA’s Area Health Resource File (approximately 890,000), and allowing for duplication in both the Medicare/Medicaid and HRSA numbers,¹⁹⁷ the Department concluded in the 2016 RIA that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.

¹⁹⁵ HRSA, Area Health Resource Files (2015), <http://ahrf.hrsa.gov>.

¹⁹⁶ Mynti Hossain and Marsha Gold, Mathematical Policy Research Inc.: Prepared for The Office of the National Coordinator for Health Information Technology, HHS, Monitoring National Implementation of HITECH: Status and Key Activity Quarterly Summary (Jan. to Mar. 2014), http://www.healthit.gov/sites/default/files/globalevaluationquarterlyreport_januarymarch2014.pdf.

¹⁹⁷ The Area Health Resource File itself double counts physicians who are licensed in more than one State.

The Department invites the public to submit information regarding physician participation in health programs or activities that receive Federal financial assistance.

(b) Programs or Activities Administered by the Department under Title I of the PPACA

This proposed rule applies to programs or activities administered by the Department under Title I of the PPACA. Such programs or activities include temporary high risk pools (section 1101), temporary reinsurance for early retirees (section 1102), Department mechanisms for identifying affordable health insurance coverage options (section 1103), the wellness program demonstration project (section 1201, adding Public Health Service (PHS) Act 2705(I)), the provision of community health insurance options (section 1323), and the establishment of risk corridors for certain plans (section 1342).

(c) Entities Established under Title I of PPACA

This proposed rule applies to the health insurance exchanges established under Title I of PPACA. Such exchanges currently include the 12 State Exchanges, 5 State Exchanges on the Federal platform and 34 Federally-facilitated Exchanges.¹⁹⁸ Title I additionally establishes State advisory councils concerning community health insurance (section 1323) and certain reinsurance entities under the transitional reinsurance program (section 1341).

(2) Entities Covered by Title IX

¹⁹⁸ CMS, State-Based Exchanges for Plan Year 2018 (Nov. 13, 2018), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/state-marketplaces.html>.

Title IX applies to recipients of Federal financial assistance for education programs or activities. 20 U.S.C. 1681. The population of applicable covered entities is defined by the term “recipient” in the Department’s Title IX regulations. The population includes any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and that operates an education program or activity that receives such assistance, including any subunit, successor, assignee, or transferee thereof. *See, e.g.*, 45 CFR 86.2. Under the definition of program or activity, recipients of Federal financial assistance within the scope of Title IX may include colleges, universities, local educational agencies, vocational education systems, or other entities or organizations principally engaged in the business of providing education. *See, e.g.*, 45 CFR part 86, appendix A (cross-referencing appendix B to 45 CFR part 80).

e. Cost Savings from Eliminating Notice and Taglines Requirement

The Department’s baseline for calculating the savings from repealing the notice and taglines requirement includes approximately \$0.632 billion in additional average annual costs from the requirement that were not considered in the 2016 rulemaking. It is important to note that, while industry estimates prompted the Department to reassess the burdens imposed by the Final Rule, the Department conducted and relied upon its own cost analysis in developing the RIA for this proposed rule.

The Final Rule assessed \$7.1 million for covered entities and \$70,400 for the Federal government in combined annual costs for printing and distributing nondiscrimination notices and taglines, with the costs being apportioned roughly equally between notices and taglines. 81 FR 31453. As explained in detail below, the Department estimates the combined notice and taglines requirement actually costs covered entities hundreds of millions of dollars per year, as explained in this analysis.

The Final Rule requires covered entities to include a notice and taglines for any “significant” document or publication, but did not define the term “significant.” 45 CFR 92.8(f)(1)(i).¹⁹⁹ Thus, covered entities have reasonably interpreted this provision to require a notice and taglines to accompany many communications from covered entities, including annual benefits notices, medical bills from hospitals and doctors, explanations of benefits from health insurance companies or health plans, and communications from pharmacy benefit managers.

Covered entities such as plan administrators and pharmacy benefit managers have reasonably interpreted this guidance to require a notice and taglines for an extraordinary amount of mailed communications, including every auto-ship refill reminder, formulary notice, and specialty benefit letter. Further, some other entities that operate in multiple States have interpreted the Final Rule as requiring them to include taglines for as many as 60 languages, or to include that many taglines in

¹⁹⁹ After publishing the Final Rule, OCR issued guidance explaining that any significant publication printed on an 8.5 x 11 sheet of paper is not considered small sized and, thus, must include a minimum of 15 taglines. See OCR, Question 23, General Questions about Section 1557 (May 18, 2017), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html>.

mailed communications due to the cost or technical barriers to customizing mailing inserts on a State-by-State basis and, thus, have incurred costs to send up to an additional two double-sided pages of notices with each communication.²⁰⁰

To estimate the volume of notices and taglines that accompany an annual benefits notice, we began with the approximately 300 million persons in the United States who have health insurance,²⁰¹ or approximately 91% of the U.S. population. The Department then assumed that the annual notice of benefits (that includes a notice and taglines) is sent to each policyholder, not to each individual member of a covered household, such as covered children. Of the total U.S. population, 306 million individuals belong to 117.7 million households. For the data set relied on, a “household” includes “all the people who occupy a housing unit. . . . The occupants may be a single family, one person living alone, two or more families living together, or any other group of related or unrelated people²⁰² who share living arrangements.”²⁰³ By implication, 17.3 million individuals do not belong to a

²⁰⁰ Although OCR has issued guidance stating that a covered entity may identify the top 15 languages spoken across all the States that the entity serves, *see* https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/aggregation_tagline/index.html, evidence of notices that some covered entities shared with OCR suggests covered entities with beneficiaries in multiple States may issue more comprehensive tagline notices exceeding 15 languages, likely because of reasonable interpretations of the relevant provisions of the Final Rule.

²⁰¹ Calculated by subtracting total uninsured population (28.1 million as of 2016), *see* <https://www.census.gov/library/publications/2017/demo/p60-260.html>, from the total U.S. Population (327,350,075 as of March 14, 2018), *see* <https://www.census.gov/popclock>.

²⁰² The calculations do not take into account households where two or more unrelated persons have individual coverage, and thus receive separate annual notices at the same household. The Department believes, however, that this exclusion has only a minor impact on the overall figures but welcome comments on whether they should be included.

²⁰³ U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf (defining “household” under “Household Type and Relationship”).

household,²⁰⁴ and live in group quarters.²⁰⁵ The Department assumed that the percentage of the U.S. population that is uninsured, 9%, is the same percentage of U.S. individuals belonging to U.S. households that are uninsured. To calculate the number of annual benefits notices, the Department added the total number of individuals that do not belong to a household (17.3 million) to the total number of households (117.7 million), and discounted the sum (135 million) by 9% to exclude those individuals who are not insured. The total number of annual notices of benefits that include a nondiscrimination notice and taglines is therefore approximately 123 million (approximately 91% of 135 million).

To estimate the volume of notices and taglines that accompany auto-renewal communications from the health insurance Exchanges, the Department assumes the Exchanges send these communications to the 11.8 million individuals enrolled in the individual market.²⁰⁶ It assumes that the Exchanges send out approximately 1.5 notices per person per year. This accounts for the annual re-enrollment communication plus additional communications Exchanges will send for

²⁰⁴ The Department subtracted 306 million individuals belonging to a household from the total US population in of 323.4 million individuals. See U.S. Census Bureau, <https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk> (relied on 2016 population nationally).

²⁰⁵ U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf (“People not living in households are classified as living in group quarters.”). “Group quarters include . . . college residence halls, . . . skilled nursing facilities, . . . correctional facilities, and workers’ dormitories.” U.S. Census Bureau, 2016 American Community Survey/Puerto Rico Community Survey Group Quarters Definitions, 1 https://www2.census.gov/programs-surveys/acs/tech_docs/group_definitions/2016GQ_Definitions.pdf.

²⁰⁶ See CMS, *Health Insurance Exchanges 2018 Open Enrollment Period Final Report* (Apr. 3, 2018), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-03.html>.

special enrollment periods. Thus, the total estimated volume of notices and taglines attributable to the Exchanges is 17.7 million.

To estimate the volume of notices and taglines that accompany hospital bills and explanations of benefits sent by insurance companies (or health plans) for hospital admissions, the Department first estimated the total number of hospital bills and explanation of benefits that would be sent to patients annually. There are 35,158,934 million hospital admissions per year.²⁰⁷ For the purpose of this estimate, the Department assumes that each admission generates three bills from one hospital visit—each of which would include a notice and tagline document, for a total of 105,476,802 bills (35,158,934 admissions times three bills per admission).²⁰⁸ The Department assumes that 10% of the 105,476,802 bills will have a notice and tagline document attached, for a total of 10,547,680 notice and tagline documents.

For patients who were insured upon admission to the hospital, in addition to the three hospital bills they would receive (on average), they would receive three associated explanations of benefits from their insurer or health plan, each of which would also include notice and tagline documents. If more than three service providers bill a patient for a hospital visit, then the savings associated with this patient encounter would be greater than estimated due to the additional notice and tagline documents that the insurer would send with each additional explanation of

²⁰⁷ CDC, Chartbook on Long-Term Trends in Health (2016), <http://www.cdc.gov/nchs/data/abus/abus16.pdf#317>.

²⁰⁸ The Department presumes one hospital visit likely will generate a bill from the physician and two bills from any combination of services, such as anesthesia, ambulance service, imaging/radiology, or laboratory or blood work.

benefits beyond the initial three assumed. If less than three service providers bill for a hospital visit, then the savings would be less due to the decreased volume of notice and tagline documents that the insurer would send given that the insurer would send fewer than three explanation of benefits. Given that approximately 91% of the U.S. population is insured, the Department estimates that approximately 32,104,054 admissions of the 35,158,934 million hospital admissions are associated with insured patients (91% of 35,158,934 million hospital admissions).²⁰⁹ This assumption does not account for variation in health care consumption between the insured and uninsured populations. It is possible that more hospital admissions are attributable to the uninsured than the insured population. If such is the case, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be lower. Further, this estimate does not account for outpatient hospital visits, which would increase the volume of notices and taglines.

As discussed further below, the Department assumes 100% of insurance companies are compliant with the notice and taglines requirement. Thus, approximately 96 million notice and tagline documents are attributable to the explanations of benefits sent by insurers (32,104,054 admissions times three explanation of benefits). Using rounded values, approximately 107 million

²⁰⁹ Calculated by subtracting total uninsured population (28.1 million as of 2016), *see* <https://www.census.gov/library/publications/2017/demo/p60-260.html>, from the total U.S. Population in 2016 (323,405,935), *see* <https://www.census.gov/popclock>. The Department also notes that Gallup recently conducted a study that shows that 12.2% of the U.S. Population is uninsured. *See* Zac Auter, U.S. Uninsured Rate Steady at 12.2% in Fourth Quarter of 2017 (Jan. 16, 2016), http://news.gallup.com/poll/225383/uninsured-rate-steady-fourth-quarter-2017.aspx?g_source=Well-Being&g_medium=newsfeed&g_campaign=tiles.

additional notices and taglines (96 million plus 11 million) are related to hospital admissions.

To estimate the volume of notices and taglines that accompany doctor's bills and explanations of benefits from a physician's visit, the Department relied on data showing that individuals visit a doctor approximately 990 million times each year.²¹⁰ Given that approximately 9%²¹¹ of Americans are uninsured, the Department assumes (and subtracting an estimated 5% for uninsured patients who do not visit the doctor, except in an emergency), 95% of individuals who see doctors every year are insured in some form. The Department assumes that each visit to a compliant doctor's office will generate at least one bill from the doctor and at least one explanation of benefits from the health insurance company. As explained below, it also assumes that 10% of doctors and 100% of insurance companies comply with the notice and taglines requirement. Thus, approximately 99 million notices and taglines are attributable to doctors billing the patients directly and approximately 941 million are attributable to explanations of benefits sent by insurers which results in a total of 1.04 billion additional notices and taglines related to physician visits. The Department seeks comment on these cost estimates, the frequency of communications to which taglines and notices are sent, and how often insurers mail

²¹⁰ CDC, Ambulatory Care Use and Physician Office Visits (2016), <https://www.cdc.gov/nchs/fastats/physician-visits.htm>. As noted above, the Department relies on the 2016 RIA assumption that virtually all doctors receive Federal financial assistance and, thus, are subject to the 2016 Final Rule.

²¹¹ Calculated by subtracting total uninsured population (28.1 million as of 2016), *see* <https://www.census.gov/library/publications/2017/demo/p60-260.html>, from the total U.S. Population in 2016 (323,405,935), *see* <https://www.census.gov/popclock>.

(other otherwise, provide copies in person or via electronic delivery) documents to the ensured.

Because experience and substantial feedback from health care insurers suggests a very high degree of compliance with the notice and taglines requirements concerning documents such as explanations of benefits, the Department has presumed 100% compliance for purposes of this RIA. Anecdotal evidence, however, suggests that hospital and physician compliance with the notice and tagline requirements in the documents discussed above is not standard industry practice. The Department estimates that, at most, 10% of such covered entities include notices and taglines in their significant mailed communications with patients. While, according to the 2016 RIA, most hospitals and physicians are covered entities under Section 1557, the Department believes their failure to adopt notices and taglines as a standard billing and communication practice may be due to the fact the notice and taglines requirement in the Final Rule mentions a duty to notify “beneficiaries, enrollees, applicants, and members of the public” and does not explicitly mention “patients.” 45 CFR 92.8(a). Additionally, the preamble to the Final Rule explained that the notice and taglines requirement covered communications “pertaining to rights or benefits” which insurance companies have universally interpreted as applying to significant numbers of communications they send to beneficiaries. 81 FR 31402. For these reasons, the Department’s calculations presume a 10% compliance rate for hospitals and physicians and a 100% compliance rate by health insurance companies concerning the notice and taglines requirement as it relates to bills and explanations of benefits, respectively.

To estimate the volume of notices and taglines that accompany pharmacy-related communications, the Department relied on estimates from the Pharmaceutical Care Management Association, which, due to the nature of its organization, obtained an estimated number of impacted beneficiaries from its member organizations. Approximately 173 million beneficiaries are being impacted annually by the notice and taglines requirement, and these beneficiaries receive between 6 and 28 communications per year with an accompanying notice and taglines. The Department relied the average of this estimate (17 communications per year per beneficiary) to determine that 2.9 billion prescription-related communications (*e.g.*, communications from pharmacy benefit managers) are sent each year.²¹²

The Department seeks comment on these calculations. In particular, it requests that commenters identify significant communications sent by covered entities that include a notice and taglines that have not been considered by this analysis, as well as the estimated annual volume for such communications. The Department also seeks comment on whether the estimates in this RIA for covered communications (communications subject to the notice and taglines requirement) by health insurance companies or pharmacy benefit managers are reasonable. The Department also seeks comment on the cost burden of, how many entities utilize, how many beneficiaries opt for receipt of, and the expected effectiveness to LEP individuals of, providing non-paper notices or taglines relevant communications related to prescriptions or explanations of benefits. The Department also seeks

²¹² Source: Pharmaceutical Care Management Association (May 2, 2017).

comment from small, community, and independent providers and pharmacy benefit managers about notices of availability of language assistance services for LEP individuals.

To calculate the costs of the notice and taglines requirement, the Department assumes that the underlying communication to which a nondiscrimination notice and taglines document is attached is a communication that is on average three sheets of paper or less. Combined with the nondiscrimination notice and taglines (which constitute another 1-4 sides of a page, that is, 1 sheet single-sided²¹³ to 2 sheets of paper double-sided), the total number of sheets of paper that would be transmitted is equivalent to 4-5 sheets of paper or less. The associated costs of the notice and taglines requirement are (1) materials, (2) postage, and (3) labor. Because of the uncertainty around some of the estimates, we report ranges for some values in this analysis.

For materials, the Department assumes that materials (paper and ink) per notice and taglines mailing insert will cost between \$0.025 and \$0.10. The Department assumes that low materials cost would be \$0.025 to print a 1-page notice and taglines on a single sheet of paper single-sided, and the high materials cost of \$0.10 to print a 4-page notice and taglines on 2 sheets of paper double sided. The Department seeks comment on its estimate of the length of the materials,

²¹³ Although this cost-benefit analysis assumes a lower-bound estimate that a notice of nondiscrimination and 15 taglines may be printed on one side of one sheet of paper, HHS believes that a notice of that length is likely noncompliant with the current Section 1557 rule requirement to be posted “in conspicuously-visible font size.” *See also* OCR, Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law (printed on two sides of one sheet of paper), <https://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf>.

including whether the required notice and taglines could have fit on one side of one page only, and how often entities did so in compliance with the requirement, as opposed to using 2-4 sides of a page.

For postage, the Department estimates that the additional weight of the notice and tagline inserts result in a range of no incremental postage costs (low-end) to \$0.21 per mailing (high-end). For instance, if an underlying communication is three sheets of paper or less, a covered entity's inclusion of one double-sided page (or shorter) of notice and taglines insert would likely weigh one ounce or less (approximately four letter-sized pages weigh one ounce).²¹⁴ Consequently, in this scenario, the notice and taglines insert would not increase the total weight of the mailing beyond the one ounce of postage that a covered entity would already expect to incur. If, however, a covered entity included 2 sheets of paper double-sided containing the nondiscrimination notice and taglines, added to a communication of three sheets of paper or more, the total weight of the mailing would likely be at least five sheets of paper, and therefore over one ounce. The marginal cost of postage for each ounce is \$0.21.²¹⁵ The Department seeks comment on whether and how often the required notice and tagline inserts are inserted in larger mailings so as not to implicate the higher end of the estimated incremental postage costs.

For labor, the Department estimates the burden to download, print, and include these notices and taglines with all significant communications for an office

²¹⁴ See "How Many Sheets of Paper Fit in a 1 Ounce Envelope for Mailing Purposes," <https://www.reference.com/business-finance/many-sheets-paper-fit-1-ounce-envelope-mailing-purposes-84ba93a60789c2e1>.

²¹⁵ See U.S. Postal Service Postage Rates, <https://www.stamps.com/usps/current-postage-rates/>

clerk (Occupation Code No. 43-9061) with a mean hourly wage of \$16.92/hour²¹⁶ plus an additional \$16.92/hour in fringe benefits, or \$33.84/hour for labor costs.²¹⁷ Based on experience, entities can manually fold and insert notices and taglines into envelopes at a rate of approximately 360 per hour. Entities that use commercial machines can fold and insert notices and taglines as fast as 5,400 envelopes per hour.²¹⁸ The Department uses the median of 2,520 notices and taglines that can be folded and placed into an envelope in an hour. Under these assumptions, the unit labor cost per notice and taglines mailing is \$0.01, or \$56.2 million per year.

Considering materials, postage and labor, the per-unit cost for the notice and taglines insert ranges from \$0.035 at the low-end (for one single-sided sheet of paper of notice and taglines) and \$0.32 at the high-end (for two double-sided sheets of paper of notice and taglines) if the Department assumes that the average underlying mailer is 3 sheets of paper. In addition, the Department estimates that some of these costs would be mitigated absent regulatory action, due to transitions to electronic delivery for some communications affected by the rule. The Department estimates electronic delivery would reduce costs of affected communications by approximately 10-20% absent regulatory action, shifting linearly from 10% in the first year to 20% in the fifth year following

²¹⁶ BLS, Occupational Employment and Wages (May 2018), https://www.bls.gov/oes/2018/may/oes_nat.htm.

²¹⁷ CMS estimates that the labor costs would be a one-time cost of \$16,244 for Medicaid managed care and a one-time cost of \$9,669 for CHIP managed care. The Department assumes for its calculations that the labor costs for the notice and tagline provisions are not one-time but are ongoing costs associated with the value of office clerks' time printing and including the notices and taglines with significant publications and significant communications.

²¹⁸ See, e.g., Pitney Bowes, Relay Mid to High Volume Inserter Systems, <https://www.pitneybowes.com/us/shipping-and-mailing/insetters-sorters-printers/relay-mid-high-volume-inserting-systems.html>.

implementation. Electronic delivery would eliminate postage costs, but may merely shift the costs of paper and printing from the entity providing the communication to the consumer/beneficiary/patient, given that some consumer/beneficiary/patient recipients of electronic communications will print them out and incur costs for the paper and ink associated with doing so. The Department has not included such consumer/beneficiary/patient costs in its estimates, but requests comments on this issue, including on whether there is a higher likelihood of electronic use than assumed here.

The Department averages the low and high-end estimates to determine a primary estimate of annual cost savings, which results in average savings of approximately \$0.632 billion per year after adjusting for electronic delivery.

These cost estimates are based on the Department's own research and extensive feedback from covered entities. It invites comment on these estimates, in particular the average numbers of pages sent by covered entities and the costs for publishing and distributing notices and taglines that may be borne by covered entities or types of transactions that it has not identified in this discussion.

With repeal of the Final Rule requirements, the Department assumes that two other regulatory requirements for taglines would also be fully repealed because they depend on, or refer to, the Final Rule for authority for the tagline requirement. The first is the requirement placed on Health Insurance Exchanges (*see* 45 CFR 155.205(c)(2)(iii)(A)), which the Department estimates issue 17.7 million communications per year, primarily through eligibility and enrollment communications. The second is the requirement placed on Qualified Health Plan

Issuers (*see* HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), whose costs are incorporated into the volume calculations for annual notices of benefits, and explanations of benefits discussed in more detail above. The Department also assumes that health insurance entities would not voluntarily append notices and taglines to routine monthly premium statements absent the Final Rule, but are doing so because of it (or because of a requirement in another regulation which bases its requirement on the Section 1557 Regulation’s requirement).

Table 2 – Annual Savings from Repeal of Requirement to Publish and Mailing Notices and Taglines, By Volume of Transactions Per Type Per Year Before Accounting for Electronic Delivery (in millions)			
	Count	Estimated Low Savings (\$0.035 /unit)	Estimated High Savings (\$0.32 /unit)
Exchange enrollment communications	17.7	\$0.62	\$5.66
Annual notice of benefits	123	\$4.32	\$39.46
Explanations of Benefits - hospital admissions	96	\$3.37	\$30.82
Explanations of Benefits - physician's visits	941	\$32.93	\$301.05
Medical bills - hospital admissions	11	\$0.37	\$3.38
Medical bills - physician visits	99	\$3.47	\$31.69
Pharmacy-related notices	2900	\$101.50	\$928.00
Subtotal, not accounting for electronic communications	4188	\$146.57	\$1,340.06

The average of the low and high end estimates yields a primary estimate of annual savings of approximately \$0.632 billion after accounting for electronic delivery. The Department assumes that the nine other CMS regulations or guidelines requiring taglines will continue to be in effect, and the cost of complying with these

CMS requirements would need to be subtracted from the total savings that the Section 1557 Regulation's rescission generates for the health care sector as set forth in Table 2. These requirements include (1) Group Health Plans and Health Insurance Issuers requirements²¹⁹; (2) Navigator requirements²²⁰; (3) Non-Navigator Assistance Personnel requirements²²¹; Medicaid requirements²²²; Medicaid Managed Care requirements²²³; CHIP requirements²²⁴; CHIP Managed Care requirements²²⁵; Hospitals Qualifying for Tax-Exempt Status requirements²²⁶; and Medicare Advantage (Part C) and Prescription Drug Plans (Part D) requirements.²²⁷ Because the Department's previous rulemaking on these CMS tagline requirements did not attempt to estimate these costs, it invites comment on cost implications here.

Other burdens imposed by the Final Rule's notice and taglines requirements are real, but difficult to quantify.

The vast majority of recipients of taglines do not require translation services. For example, according to Census statistics, as of 2015, over three-quarters (79%) of the U.S. population over age 18 speak only English at home, followed by Spanish (12.5%).²²⁸ Additionally, of persons selecting a language preference when

²¹⁹ 45 CFR 147.136(e)(2)(iii) and (e)(3), and 147.200(a)(5).

²²⁰ 45 CFR 155.215(c)(4).

²²¹ 45 CFR 155.215(c)(4).

²²² 42 CFR 435.905(b)(3).

²²³ 42 CFR 438.10(d)(2) through (3), (d)(5)(i) and (iii), and (j).

²²⁴ 42 CFR 457.340(a).

²²⁵ 42 CFR 457.1207.

²²⁶ 26 CFR 1.501(r)-4(b)(5)(ii).

²²⁷ Medicare Marketing Guidelines § 30.5.1, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>.

²²⁸ U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over, 2011 – 2015 American Community Survey* (American FactFinder) (2017),

registering for coverage on the HealthCare.gov platform for 2017, 89.93% selected English, followed by 8.36% who selected Spanish.²²⁹ These data points indicate that, for the large majority of people who receive them, the required language tagline mailings provide little to no benefit because they are already proficient English speakers with little need for, and no entitlement under the law to, translation services.

The Department has received many communications from beneficiaries and advocacy groups complaining about the excessive amount of paperwork they receive. These individuals and groups have explained that few people read the notice and taglines and most ignore the last pages of lengthy health documents. These complaints make us concerned that the Section 1557 Regulation has resulted in “cognitive overload,” such that individuals experience a diminished ability to process information when inundated with duplicative information and paperwork.

Additionally, documents that contain a significant number of pages that recipients do not value will induce annoyance or frustration due to perceived wasting of time, ignorance of the customers’ actual needs or language abilities, waste of economic resources, or insensitivity to environmental concerns. These

https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US. See also Kimberly Proctor, Shondelle M. Wilson-Frederick, et al., *The Limited English Proficient Population: Describing Medicare, Medicaid, and Dual Beneficiaries*, 2.1 Health Equity 87 (May 1, 2018), <http://online.liebertpub.com/doi/10.1089/heq.2017.0036> (identifying Spanish as the language of the largest majority of limited English proficient speakers in Medicaid and Medicare, according to the 2014 American Community Survey).

²²⁹ CMS, *Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period* (April 2017), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf>. States that that do not use the HealthCare.gov platform, such as California and New York, were not included in this report.

frustrations, though difficult to quantify are reasonable to expect, given the large volume of health care communications with notice and taglines that most Americans receive. It is also reasonable to expect that repeated mailings of taglines to people who do not want them may negatively impact their likelihood to read truly significant documents from their insurers or doctors, and may negatively impact health outcomes in some cases.

The Department seeks comment on whether and how the Final Rule's notice and taglines requirements impose costs on covered entities and other downstream entities and individuals.

f. Costs Arising from Removal of Notice and Taglines Requirement

Repealing the notice and taglines requirement 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. Even so, such an impact is expected to be negligible. Reports from covered entities suggest, anecdotally, that utilization of translation services did not appreciably rise after the Final Rule's imposition of notice and taglines requirements.²³⁰ Furthermore, the Section 1557 requirement added 47 languages to existing language access requirements, which only increased access to 0.4% of the entire U.S. population. This is after broadly defining "limited English proficiency" to include those who speak English "well" but not "very well."²³¹ The Department's Office for Civil Rights also produced a list of the

²³⁰ Source: Aetna (May 1, 2017).

²³¹ See HHS OCR, Frequently Asked Questions to Accompany the Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency under Section 1557 of the Affordable Care Act, Question 2 (Sept. 1, 2016), <https://www.hhs.gov/civil-rights/for->

top 15 languages in each State; however 26 of the languages on OCR's list are not spoken by even 0.004 percent of the population. In some States, especially those with sparser populations, health insurance issuers must provide tagline services in languages spoken by very few people in the State. For instance, in Wyoming, issuers must provide translation notices in Gujarati and Navajo in every significant communication sent to beneficiaries to account for approximately 40 Gujarati speakers and 39 Navajo speakers; in Montana issuers must provide notices to account for approximately 80 speakers of Pennsylvania Dutch; and in Puerto Rico, issuers must provide taglines notices to account for approximately 22 Korean speakers and 22 French Creole speakers.²³² In addition, the Section 1557 Regulation omitted some languages, like Hungarian, spoken by significant numbers of people in more densely populated States.

Regulations under Section 504 of the Rehabilitation Act require the provision of auxiliary aids and services in health programs or activities that receive Federal financial assistance. 45 CFR 84.52(d). Because the notice requirement under the Final Rule requires frequent mailed notification of the availability of auxiliary aids and services, repealing the notice of nondiscrimination requirement may result in additional societal costs, such as decreased utilization of auxiliary aids and services

[individuals/section-1557/1557faqs/top15-languages/index.html](#) (using 2013 year estimates). See U.S. Census Bureau, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over, https://factfinder.census.gov/faces/tables/serices/jsf/pages/productview.xhtml?pid=ACS_14_5YR_B16001&prodType=table (2016 year estimates).

²³² OCR, Resource for Entities Covered by Section 1557 of the Affordable Care Act, Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 States, the District of Columbia, and the U.S. Territories (Aug. 2016), <https://www.hhs.gov/sites/default/files/resources-for-covered-entities-top-15-languages-list.pdf>.

by individuals with disabilities due to their reduced awareness of such services. This impact may be limited, however, because the Section 504 regulations already require recipients of Federal financial assistance employing fifteen or more persons provide notice to participants, beneficiaries, applications, employees, and other interested persons of the availability of such aids and services. 45 CFR 85.12 and 84.22(f).

Additionally, an unknown number of persons are likely not aware of their right to file complaints with the Department's Office for Civil Rights and some unknown subset of this population may suffer remediable grievances, but will not complain to OCR absent notices informing them of the process.

g. Cost Savings from Changes to Language Access Plan Provisions

Although the Final Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director "shall" take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would develop and implement a language access plan following issuance of the Final Rule. 81 FR 31454.

OCR estimated that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is

estimated to be \$109.36 based on Bureau of Labor Statistics (BLS) data for 2018.²³³ The Department estimated that approximately 269,141 entities could potentially make changes and develop language access plans, as part of the requirement to take reasonable steps to provide meaningful communication with LEP individuals (calculated by reducing the total number of entities (275,002) by the number of hospitals and nursing care facilities that were already subject to language access plan requirements under Medicare Part A (5,861). The Department further assumed that only 50% of the identified entities would actually make changes to implement a language access plan. These assumptions imply that the total cost of developing language access plans will be approximately \$44.1million (269,141 entities multiplied by 50% of entities multiplied by 3 hours per entity multiplied by \$109.36 per hour) in the first year and approximately \$14.7 million (269,141 entities multiplied by 50% of entities multiplied by 1 hour per entity multiplied by \$109.36 per hour) per year in subsequent years. In making these calculations, the Department assumes sunk costs cannot be recovered by this rule, and therefore that initial language access plan development costs described above cannot be recovered.

By repealing the provision of the Final Rule regarding the Language Access Plans, the Department estimates an annual savings are \$14.7 million.

h. Cost Savings Attributed to Covered Entities' Handling of Certain Grievances

²³³ BLS, Occupational Employment and Wages (May 2018), https://www.bls.gov/oes/2018/may/oes_nat.htm.

The proposed rule proposes to repeal the requirement for each covered entity with 15 or more employees to have a compliance coordinator and a written grievance procedure to handle complaints alleging violations of Section 1557. The Department estimates that, under the proposed rule, covered entities would no longer have to incur certain labor costs associated with processing grievances related to sex discrimination complaints as they relate to gender identity and sex-stereotyping as defined under the Final Rule because such definitions would be repealed and no longer binding under the proposed rule. This proposed repeal would not, however, affect the independent obligations of Section 1557 covered entities to comply with Federal regulations under Section 504 and Title IX to have written processes in place to handle grievances alleging certain disability and sex discrimination claims, respectively.²³⁴

For the sake of consistency and convenience, the Department uses the methodology from the 2016 Final Rule as a foundation for estimating the projected savings of this proposed rule provision.

The 2016 Final Rule estimated that, in years three through five of the Final Rule's implementation, covered entities with 15 or more employees would incur \$85.5 million in costs annually to handle Section 1557 grievances. 81 FR 31458. This estimate assumed that covered entities would experience an average increase in grievances equal to OCR's projected long-term increase in caseload of about 1%. 81

²³⁴ See, e.g., 45 CFR 84.7(a) (HHS regulations implementing Section 504) (requiring a written process in place for handling grievances alleging disability discrimination), 86.8(a) (HHS regulations implementing Title IX) (requiring a written process in place for handling grievances alleging sex discrimination).

FR 31376. The 2016 Final Rule monetized this 1% increase in caseload as a labor cost equivalent to 1% of the annual median wage for a medical and health service manager (occupation code 11-9111). 81 FR 31376. The Department continues to assume that OCR's increase in caseload attributed to the 2016 Final Rule reasonably informs the increase in grievance processing that covered entities experience.

Based on OCR's tracking of Section 1557 complaints received from promulgation of the Final Rule (May 18, 2016) until present, OCR predicts that its long-term caseload would have increased 5% rather than 1% as originally predicted. Further, OCR believes roughly 60% of this increase (which equals 3% of the overall increase) would have been attributable to discrimination claims based on the Final Rule's definition of sex discrimination with respect to gender identity and sex stereotyping. The Department uses the phrase "would have" with regard to OCR's caseload because, as described above, the Department has been enjoined by a Federal court from enforcing claims based on the Final Rule's novel definition of sex discrimination.

The Final Rule asserted that private parties have the right to challenge a violation of Section 1557 or the Final Rule in Federal court, independent of OCR enforcement or involvement. 45 CFR 92.302(d). In the preamble to the Final Rule, the Department estimated that the ability for private parties to sue under the Final Rule would result in covered entities bearing increased compliance costs. 81 FR 31395 ("the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution,

oftentimes prior to an individual bringing a private right of action.”). The injunction does not apply to suits filed by private parties.

Although the Supreme Court has recognized a private right of action for some civil rights statutes enforced by the Department, with the proposed rule change, the Department would no longer assert that a private right of action exists for parties to sue covered entities for any and all alleged violations of the proposed rule. The Department would no longer take a position on that issue in its regulations, leaving the matter as primarily one for the courts to decide. Additionally, by virtue of rescinding the definitions from the regulatory text, the proposed rule would remove the expansive inclusion of gender identity and sex stereotyping in the definition of sex discrimination as substantive grounds for a private right of action alleging such violations by covered entities. As a result, a certain number of covered entities that are currently incurring grievance-related costs related to these claims may no longer incur such costs under the proposed rule.

For reasons set forth above, the Department estimates that covered entities have experienced a 3% increase in grievance claims over the long term concerning gender identity and sex stereotyping claims as set forth under the Final Rule and that, under the proposed rule, they would no longer have to process such claims under the grievance procedures required under the Final Rule. However, due to voluntary policies or more stringent State requirements, the Department expects that 50% of covered entities would likely continue to accept and handle grievances alleging discrimination based on gender identity and sex stereotyping as set forth under the Final Rule, notwithstanding that this proposed rule would eliminate those

provisions. Consequently, the Department estimates that only approximately half of the 3% increase in caseload, or about 1.5%, will be realized as annual savings by covered entities. The annual savings in labor attributed to a 1.5% decrease in grievance caseload is \$123.4 million. This value represents 1.5% of the annual median wage of a medical and health service manager (\$199,472 fully loaded) multiplied by the 41,250 covered entities with 15 or more employees.

i. Additional Costs for Training and Familiarization under Proposed Rule

To comply with the proposed rule, the Department anticipates that some covered entities may incur costs to re-train employees in order realize potential longer term costs savings from the deregulatory aspects of this proposed rule change, for example, provisions eliminating the need for certain grievance procedures described in the preceding section. The Department assumes that employers are most likely to train employees who interact with the public, and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, the Department assumes that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. It uses the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, the Department does not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

(1) Number of Covered Entities That May Train Workers

The Final Rule estimated that 275,002 covered entities would train their employees on the Rule’s requirements in general (including training regarding language access provisions), and used that 275,002 figure as the basis for calculating costs to covered entities arising specifically out of the Rule’s prohibition on discrimination on the basis of sex. *See* 81 FR at 31450. HHS assumes, for purposes of this analysis, that the Final Rule’s estimation was an accurate and reasonable basis for calculating costs arising out of the Final Rule’s prohibition of sex discrimination. However, HHS seeks comment on the accuracy of these assumptions and calculations.

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180
	Navigator grantees	100
	Total Entities	275,002

(2) Number of Individuals Who Will Receive Training

The first category of health care staff that may receive training comprises health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The BLS occupational code for this grouping is 29-1000 and the 2018 reported count for this occupational group is approximately 5.4 million with average loaded wages of \$98.04 per hour.

The second category of health care staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29-2000) and accounts for 3.1 million workers with average loaded wages of \$46.52 per hour. Technicians work in almost every area of health care: x-ray to physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31-0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. The Department refers to this workforce as non-degreed compared to medical technicians who generally have degrees or certificates. There are approximately 4.1 million individuals employed in these occupations with average loaded wages of \$31.14 per hour.

The fourth category of health care staff that the Department assumes will receive training is health care managers (approximately 0.4 million based on BLS data for occupation code 11-9111) with average loaded wages of \$109.36 per hour. Because the Department assesses costs of familiarization with the regulation for one manager at each entity, it assumes that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of health care staff that the Department assumes will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43-0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.8 million individuals were employed in these occupations in health facilities in 2018 with average loaded wages of \$36.50 per hour. The Department assumes that outreach workers are included in the five categories listed above, especially in the manager category.

(3) Total Cost of Training

The Final Rule estimated that covered entities would incur \$420.7 million in undiscounted costs to train employees on the requirements of the Rule, distributed roughly evenly over the first two years after the Final Rule's effective date. 81 FR at 31458. This conclusion presumed covered entities were already periodically training employees on their obligations under Section 1557, but that the Final Rule's new sex discrimination requirements would induce covered entities to engage in additional "comprehensive training." 81 FR 31447.

For the purposes of this regulatory impact analysis, the Department assumes covered entities would face similar costs to retrain the workforce on the proposed rule's requirements.²³⁵ However, because some covered entities will avoid incurring training expenses when they are not required to (and they will not be under the proposed rule), and because several States with large populations already prohibit gender identity discrimination in health care, the Department further assumes that only 50% of covered entities would modify their policies and procedures to reflect the changes in the proposed rule. The Department further assumes that the same percentage, 50%, of covered entities, or 137,501, would train their employees to reflect the changes in the proposed rule. As in the Final Rule, the Department assumes that approximately half of the employees at these covered entities will engage in an average of an additional hour of training, and that this will occur in the first year of implementing this rule. These assumptions imply total training costs of \$235.9 million. The Final Rule's calculations of training costs did not anticipate any ongoing training costs after year one – either in the form of annual refresher training for returning employees or training for new employees. The Department now believes that covered entities likely incur such costs, but assumes that equal costs would also be incurred under the proposed rule. Therefore, HHS has excluded ongoing training costs from the calculation of the baseline and from the calculation of the projected costs of the proposed rule, because such training has a net zero

²³⁵ Training costs in the Final Rule relied upon 2014 wages. *See, e.g.*, 81 FR 31451 (estimating the median hourly wage for occupation code 29-1000 at \$36.26, unloaded, at https://www.bls.gov/oes/2014/may/oes_nat.htm#29-0000<https://www.bls.gov/oes/tables.htm> (OES Data: May 2014). https://www.bls.gov/oes/2014/may/oes_nat.htm#29-0000https://www.bls.gov/oes/2014/may/oes_nat.htm#29-0000).

effect on projected costs. HHS solicits comment on the foregoing assumptions and calculations of the costs of training under the Final Rule and the proposed rule.

j. Additional Costs for Revising Policies and Procedures

As discussed above, the Department anticipates that 50% of covered entities, or approximately 137,501 entities, would choose to revise their policies or procedures to reflect this proposed rule's clarification of the application of Section 1557 (if finalized as proposed), while other covered entities may retain their policies to ensure compliance with State or local laws. The Department assumes that it would take, on average, three to five hours for a provider to modify policies and procedures concerning the Section 1557 proposed rule. The Department selects four hours, or the midpoint of this range, for the analysis. HHS further assumes that an average of three of the hours would be spent by a mid-level manager equivalent to a front-line supervisor (Occupation code 43-1011), at a cost of \$57.06 per hour²³⁶ after adjusting for overhead and benefits, and an average of one hour would be spent by executive staff equivalent to a general and operations manager (Occupation code 11-1021), at a cost of \$119.12 per hour²³⁷ after adjusting for overhead and benefits. HHS solicits comment on the accuracy of these assumptions. The total cost for the estimated 137,501 covered entities to make their policies and procedures consistent with the proposed rule's clarification of discrimination on the basis of sex is estimated to be approximately \$39.9 million following implementation of this rule.

²³⁶ BLS, Occupational Employment and Wages, May 2018, https://www.bls.gov/oes/2018/may/oes_nat.htm.

²³⁷ *Id.*

The above estimates of time and number of entities that would choose to revise their policies under the regulation are approximate estimates based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would choose to revise their policies under the regulation is difficult to calculate.

k. Other Costs Due to Reversion to Previous Practices

The Final Rule may have prompted covered health care providers to institute operational changes beyond their nondiscrimination policies and procedures. HHS solicits comment on providers' experience with the efficiency or cost-effectiveness of any such operational changes made in response to the Final Rule. To the extent that such changes required more than a *de minimis* cost to implement, providers that choose to revert to previous practices may incur more than a *de minimis* cost in making that reversion. However, as such changes would likely be voluntary, HHS assumes that providers would make such changes because they determined them to be cost-effective. HHS solicits comment on the accuracy of this assumption.

l. Other Benefits or Costs

The Final Rule's regulatory impact analysis did not include an economic cost-benefit analysis of the impact of the regulation on health insurance benefit design. The Department lacks sufficient data on how much burden the Final Rule has placed on the development and operation of insurance benefits policies, and, thus, is unable to fully assess the benefit of removing this requirement. The Final Rule was intended to impact benefit design by applying Section 1557's nondiscrimination

requirements to denial, cancellation, limitation, refusal to issue, refusal to renew, or categorical exclusion of certain benefits related to gender identity. A Federal court, however, enjoined application of the Final Rule in this manner on a nationwide basis immediately before the start of the first plan year after the Final Rule came into effect, thus, OCR has not enforced the Final Rule's benefit design provisions as they relate to coverage of gender identity-related treatments.

The Department does not know what effect the Final Rule, in conjunction with the court injunction, has had on benefit design with respect to coverage of gender identity-related treatments. It, therefore, does not have enough information to estimate effects from the proposal to repeal of the Final Rule's benefit design requirements. The Department believes, however, that because a Federal court enjoined enforcement of the Section 1557 Regulation before the start of the first plan year in which the current rule would have applied, that beneficiaries of the expanded gender identity provisions could not have developed a reliance interest on the enjoined parts of the rule. The Department seeks comments on the effective date of repeal of the gender identity benefit design provisions.

Additionally, aside from benefit design questions, the Department seeks comment and documentation of cases where, despite the preliminary injunction barring OCR from enforcing the provisions, persons would not have received treatments or procedures related to gender identity or termination of pregnancy, but for the Final Regulation's gender identity and termination of pregnancy provisions.

The Department does not estimate any cost savings related to decreased OCR enforcement of gender identity related claims under the proposed rule because the injunction has generally prevented OCR enforcement of such claims to date and the proposed rule would thus merely reflect the *status quo* and not result in additional cost savings related to OCR enforcement expenditures.

Continued enforcement of Section 1557 includes vindication of legal rights, the benefits of which are difficult to quantify. The proposed rule would continue to prohibit covered entities from discriminating against patients and beneficiaries on the basis of their race, color, national origin, disability, age, or sex. OCR will continue to vigorously enforce civil rights in order to help guarantee more access to health care and concomitant improved health outcomes—but these benefits are difficult to estimate given that many of the prohibitions encompassed by the proposed rule, as with the Final Rule, have been in place at the Federal level for many years or have been otherwise required by State or local law. We welcome comments on these issues.

7. Impact on State, Local, and Tribal Entities under Executive Orders 12866, 13132, and 13175

a. State and Local Governments

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent Final Rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Executive Order 13132, 64 FR 43255 (Aug. 4, 1999). The Department does not believe that this rulemaking would (1)

impose substantial direct requirements costs on State or local governments; (2) preempt State law; or (3) otherwise have federalism implications. Section 1557 itself provides that it shall not be construed “to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a) [of Section 1557].” 42 U.S.C. 18116(b).

The proposed rule maintains the full force of Federal civil rights laws’ protections against discrimination, but does not attempt to impose a ceiling on how those protections may be observed by States. State and local jurisdictions would continue to have the flexibility to impose additional civil rights protections.

The Department believes that there would be reduced costs to State and local entities, by repealing wasteful Federal mandates and giving States more flexibility to address the needs of LEP individuals or other regional-specific issues.

The Department believes that the proposed change to its Title IX regulations would not have a substantial direct effect on the States, on the relationship between the national government and the States, on the distribution of power and responsibilities among the various levels of government, or on tribal self-government or sovereignty. The proposed rule would not subject Title IX funding recipients to new obligations, but rather would relieve potential burden on the States or tribes that could have resulted from the prior interpretation of Title IX by HHS. The proposed rule would allow States and tribes to adopt or continue to provide nondiscrimination protections on the basis of sexual orientation and gender identity in State, local, and tribal law. Therefore, the Department has determined that the proposed rule would not have sufficient federalism implications to warrant

the preparation of a federalism summary impact statement under Executive Order 13132, and that the rule would not implicate the requirements of Executive Orders 12866 and 13175 with respect to tribes.

b. Tribal Governments

Executive Order 12866 directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions. Executive Order 12866 at section 6(a)(3)(B).²³⁸ Executive Order 13175 further directs that Agencies respect Indian tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet the responsibilities that arise from the unique legal relationship between the Federal Government and Indian tribal governments. Executive Order 13175 at section 2(a). The Department does not believe that the proposed rule would implicate the requirements of Executive Orders 12866 and 13175 with respect to tribal sovereignty, and solicits comments from tribal representatives and tribal members on this conclusion and all other provisions of this proposed rule as they relate to tribes.

8. Avoidance of Inconsistent, Incompatible, or Duplicative Regulations

Executive Order 12866 requires the Department to avoid issuing regulations that are inconsistent, incompatible, or duplicative with other regulations that it has issued or that have been issued by other Federal agencies. Executive Order 12866 at section 1(b)(10). Section 1557 itself requires avoidance of duplication by providing that the enforcement mechanism under specifically identified civil rights laws “shall

²³⁸ As stated in the preceding section, the proposed rule does not have federalism implications.

apply for purposes of violations” of Section 1557. 42 U.S.C. 18116(a).²³⁹ The preamble to the Final Rule repeatedly stated that, with the exception of issues concerning notices, sex discrimination, and language access plans, it was merely applying civil rights protections that were already applicable and familiar to covered entities. *See* 81 FR 31446. (“It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years.”); 81 FR 31464 (“For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal.”).

With regard to the current Section 1557 Regulation’s notice and taglines requirement, covered entities are already subject to dozens of regulations concerning multi-language taglines or notices concerning an individual’s right to have documents translated. For example, CMS imposes tagline requirements on health insurance marketplaces, qualified health plan issuers, group health plans and health insurance issuers, navigators, non-navigator assistance personnel, Medicaid, Medicaid managed care, Children’s Health Insurance Program, Medicare Advantage, and Medicare Part D.²⁴⁰ Furthermore, a Department of Treasury regulation imposed

²³⁹ For the applicable enforcement mechanisms, *see* 45 CFR parts 80 and 81 (Title VI), 85 (Section 504), 86 (Title IX), 90 and 91 (Age Act).

²⁴⁰ 45 CFR 147.136(e)(2)(iii) and (e)(3) and 147.200(a)(5) (requiring group health plans and QHP issuers to post taglines in languages in which 10% of individuals with LEP county-wide are exclusively literate on internal claims and appeals notices, and requiring QHP issuers to post on its Summary of Benefits and Coverage), 155.215(c)(4) (requiring Navigators and non-Navigator personnel in States with Marketplaces operated by HHS to “[p]rovide oral and written notice to consumers with LEP, in their preferred language, informing them of their right to receive language assistance services and how to obtain them”); 42 CFR 435.905(b)(3) (Medicaid regulations requiring

tagline requirements for hospital organizations to qualify for tax-exempt status.²⁴¹

Additionally, in 2003, the Department issued guidance under Title VI of the Civil Rights Act of 1964, setting forth a flexible four-factor framework to assess the necessity and reasonableness for providing written translation for LEP individuals.

²⁴² Finally, the PPACA itself provides that each summary of benefits and coverage provided by issuers—perhaps the single most important health insurance-related document a person receives—must be “presented in a culturally and linguistically appropriate manner.” 42 U.S.C. 300gg-15(b)(2).

individuals to be “informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services”); 438.10(c)(5)(i) through (ii) (Medicaid managed care regulations requiring taglines until July 1, 2017); 438.10(d)(2) through (3), (d)(5)(i), (d)(5)(iii) and (d)(5)(j) (Medicaid managed care regulations requiring taglines on “all written materials for potential enrollees” in the prevalent non-English languages in the State and requiring notification that “oral interpretation is available for any language and written translation is available in prevalent languages” during the rating period for contracts with managed care entities beginning on or after July 1, 2017), 457.340(a) (applying certain Medicaid requirements to the Children’s Health Insurance Program, including § 435.905(b)(3), which requires individuals to be “informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services”), 457.1207 (applying certain Medicaid managed care requirements to Children’s Health Insurance Program managed care, including § 438.10(c)(5)(i)-(ii) until the State fiscal year beginning on or after July 1, 2018), § 438.10(d)(2)-(3), (d)(5)(i), (iii), (j) (applying certain Medicaid managed care requirements to Children’s Health Insurance Program managed care, in the State fiscal year beginning on or after July 1, 2018); CMS, 2017 Medicare Marketing Guidelines, § 30.5.1, § 100.2.2, § 8, § 80-8 (Jun. 10, 2016), <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf> (providing a CMS Multi-Language Insert” for certain Medicare Advantage Plan’s and Medicare Part D Plan Sponsors’ marketing materials meeting the percentage translation threshold in §§ 422.2264(e) and 423.2264(e) of Title 42 of the CFR). As discussed in the RIA section of this NPRM, we presume 45 CFR 155.205(c)(2)(iii)(A) (requiring Marketplaces and QHP issuers to post taglines on their websites and documents “critical for obtaining health insurance coverage or access to health care services through a QHP”) and other provisions that depend or refer to 45 CFR part 92 for their tagline requirements would no longer apply if this proposed rule is finalized.

²⁴¹ See 79 FR 78954 (Dec. 31, 2014) (finalizing rule requiring the plain language summary of the financial assistance policy for hospital organizations to qualify as tax exempt, to indicate, if applicable, whether the summary, the financial assistance policy, and the application for such assistance are available in other languages).

²⁴² Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47315 (Aug. 8, 2003) (HHS LEP Guidance).

Substantially replacing many provisions of the Final Rule as proposed, including removing the notice and taglines requirements, would eliminate significant redundancies identified above, while maintaining vigorous enforcement of existing Federal civil rights statutes.

B. Executive Order 13771 on Reducing and Controlling Regulatory Costs

This proposed rule is expected to be an E.O. 13771 deregulatory action. The Department estimates that this proposed rule would generate \$532 million in net annualized savings at a 7% discount rate (discounted relative to year 2016, over a perpetual time horizon, in 2016 dollars).

Furthermore, Executive Order 13765 states that “the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [PPACA] shall exercise all authority and discretion available to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [PPACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, [or] purchasers of health insurance.” Executive Order 13765, 82 FR 8351, 8351 (Jan. 24, 2017). In implementing Section 1557 of the PPACA, the Section 1557 Regulation imposed significant regulatory burdens on covered entities, including States, healthcare providers, and health insurers, without corresponding benefits for patients or beneficiaries. By proposing to substantially replace the Final Rule with a regulation that requires compliance with pre-existing civil rights laws, the Department is acting in accordance with

Executive Order 13765 in exercising its authority and discretion to address the fiscal burdens on States, and the regulatory burdens imposed on individuals, families, healthcare providers, health insurers, patients, and recipients of healthcare service. The proposed rule would particularly reduce the economic burden imposed on health care providers and insurers required to provide taglines under the Final Rule. Decreasing the burden on these providers and insurers will allow them to pass along some of the cost savings to individuals, families, patients, and beneficiaries of insurance to whom they provide services or coverage. Additionally, eliminating the taglines requirement will alleviate burdens on patients and insurance beneficiaries that neither need nor want to receive repeated tagline mailings.

C. Congressional Review Act

The Congressional Review Act (CRA) defines a “major rule” as “any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” 5 U.S.C. 804(2). Based on the analysis of this proposed rule under Executive Order 12866, this proposed rule, if finalized as proposed, is expected to be a major rule for purposes of the Congressional Review

Act because it proposes cost savings of over \$100 million. The Department will comply with the CRA's requirements to inform Congress if applicable.

D. Unfunded Mandates Reform Act

The proposed rule is not subject to the Unfunded Mandates Reform Act because it falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability. 2 U.S.C. 1503(2).

E. Regulatory Flexibility Act and Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Pub. L. 96-354, 94 Stat. 1164 (Sept. 19, 1980) (codified at 5 U.S.C. 601 through 612). The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the proposed rule will not have a significant economic impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would minimize the economic impact of the proposed rule on small entities. 5 U.S.C. 603(c).

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a

significant impact on a substantial number of small entities if it has at least a three percent impact of revenue on at least five percent of small entities.

Based on its examination, the Department has preliminarily concluded that this proposed rule does not have a significant economic impact on a substantial number of small entities. The preamble to the Final Rule discussed the character of small entities impacted by the Final Rule in detail. 81 FR 31463-31464. Although the proposed rule would affect numerous small entities, it does not create new or expanded requirements, and, for all the reasons stated in the RIA, it will be reducing economic burdens on such entities overall. The proposed changes to Title IX would not impose any new substantive obligations on Federal funding recipients and, in fact, would provide regulatory clarity and relief for any small entities previously subject to several of the policies and requirements imposed by the Department.

To the extent the proposed rule imposes economic costs, it is limited to entities' voluntary choices to revise their policies and procedures and conduct training, and we believe these costs are well below those required to have a significant impact on a substantial number of small entities. In addition, the majority of the costs associated with this proposed rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact.

For these reasons, the Secretary certifies that the proposed rule will not have a significant impact on a substantial number of small entities.

Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking reinforces the requirements of the RFA and requires the Department to

notify the Chief Counsel for Advocacy of the Small Business Administration if the proposed rule may have a significant economic impact on a substantial number of small entities under the RFA. Executive Order 13272, 67 FR 53461 (Aug. 16, 2002). Because the economic impact of the proposed rule is not significant under the RFA, the Department is not subject to Executive Order 13272's notification requirement.

F. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Pursuant to Executive Order 12250, the Attorney General has the responsibility to "coordinate the implementation and enforcement by Executive agencies of...Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)" Executive Order 12250 at sec. 1-2(b), 45 FR 72995 (Nov. 2, 1980). Furthermore, Executive Order 12250 requires the Attorney General to "review... proposed rules... of the Executive agencies in order to identify those which are inadequate, unclear or unnecessarily inconsistent." *Id.* at sec. 1-202. The proposed rule has been reviewed and approved by the Attorney General pursuant to Executive Order 12250.

G. Paperwork Reduction Act

The Department has determined that the proposed rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* If the rule is finalized as proposed, OCR will update and revise its burden analysis by removing the burden associated with the posting of a nondiscrimination notice and taglines, development and implementation of a language access plan, and designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or

more employees. OCR is seeking Paperwork Reduction Act approval for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form)²⁴³ separate from this rulemaking.

VII. Effective Date

Because this proposed rule would relieve significant regulatory burdens, particularly the tagline requirements, the Department proposes that the effective date be 60 days after publication of the Final Rule.

VIII. Request for Comment

The Department seeks comment on all issues raised by the proposed regulation. Specifically, in addition to issues on which it has already requested comments, above, the Department requests comment on:

- The financial impact of the proposed rule on the health care sector, with any detailed supporting information, facts, surveys, audits, or reports;
- Whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and rights of protected classes;
- Whether the Final Rule's grievance procedures have achieved any significant mitigation of the costs of litigation over the new requirements created by the Final Rule;
- Whether, and if so, how new and developing technologies can assist covered entities with their compliance obligations and enhance access to quality health care;
- The costs incurred for design of health benefits, with any detailed information facts, surveys, audits, or reports;

²⁴³ See HHS OCR, Assurance of Compliance Portal, <https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf>.

- The costs to provide nondiscrimination notices and taglines, specifically including the marginal labor, material, postage, and depreciation costs for printing and mailing additional sides and sheets of paper (including extra postage), the volume of such notices or mailings, and the impact of such notices or mailings on the utilization of language access services with any detailed supporting information, facts, surveys, audits, or reports;

- The prevalence of health care entities that operate and beneficiaries that reside in more than one State, with any detailed supporting information, facts, surveys, audits, or reports;

- The amount of marketing, enrollment, and benefits communications delivered or mailed per year, with any detailed supporting information, facts, surveys, audits, or reports;

- Unaddressed discrimination on the basis of race, color, national, and origin, sex, disability, and age as applied to State and Federally-facilitated Exchanges, with any detailed supporting information, facts, surveys, audits, or reports;

- Whether covered entities seek guidance on best practices for compliance with Section 1557, such as for civil rights assurances signed by recipients of Federal financial assistance, and notices of civil rights posted in areas such as employee break rooms;

- The costs of coming into compliance or remaining in compliance with a Federal prohibition of discrimination on the basis of gender identity or sexual orientation under Title IX, and with any detailed supporting information, facts, surveys, audits, or reports;

- Whether the proposed LEP provisions are practical, effective, fiscally responsible, reasonable, responsive to the particular circumstances relevant to health care programs or activities, and capable of being readily implemented;
- Whether HHS's Title VI regulations at 45 CFR Part 80 should be amended to address the *Lau v. Nichols* precedent applicable to LEP individuals under any program or activity receiving Federal financial assistance from HHS;
- Whether HHS's Section 504 regulations at 45 CFR Part 85 should be amended to address effective communication, accessibility standards for buildings of facilities, accessibility of electronic information technology, and the requirement to make reasonable modifications for otherwise qualified individuals with disabilities under any program or activity receiving Federal financial assistance from HHS; and
- Whether the proposed provisions on language assistance services adequately balance an LEP individual's meaningful access to effectively participate in the covered health program or activity with the resources available and costs to the covered entity.

List of Subjects

42 CFR Part 438

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 440

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Sex discrimination.

42 CFR Part 460

Age discrimination, Aged, Civil rights, Discrimination, Health Incorporation by reference, Individuals with disabilities, Medicare, Medicaid, National origin, Nondiscrimination, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 86

Civil rights, Colleges and universities, Employment, Administrative practice and procedure, Buildings and facilities, Education of individuals with disabilities, Education, Educational facilities, Educational research, Educational study programs, Equal educational opportunity, Equal employment opportunity, Graduate fellowship program, Grant programs—education, Individuals with disabilities, Investigations, Reporting and recordkeeping requirements, Sex discrimination, State agreement program, Student aid, Women.

45 CFR Part 92

Administrative practice and procedure, Age discrimination, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs or activities, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 147

Age discrimination, Civil rights, Discrimination, Health care, Health insurance, Individuals with disabilities, National origin, Nondiscrimination,

Reporting and recordkeeping requirements, Sex discrimination, State regulation of health insurance.

45 CFR Part 155

Actuarial value, Administration and calculation of advance payments of the premium tax credit, Administrative practice and procedure, Advance payments of premium tax credit, Age discrimination, Civil rights, Cost-sharing reductions, Discrimination, Health care access, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Plan variations, Reporting and recordkeeping requirements, Sex discrimination, State and local governments.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of premium tax credit, Advertising, Advisory Committees, Age discrimination, Brokers, Civil rights, Conflict of interest, Consumer protection, Cost-sharing reductions, Discrimination, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, National origin, Nondiscrimination, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR parts 438, 440, and 460 and 45 CFR parts 86, 92, 147, 155, and 156 as follows:

Title 42—Public Health

PART 438—MANAGED CARE

1. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

2. Amend § 438.3 by revising paragraph (d)(4) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(d) * * *

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

* * * * *

3. Amend § 438.206 by revising paragraph (c)(2) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally

competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

4. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

5. Revise § 440.262 to read as follows:

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

6. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l, 1395eee(f), and 1396u-4(f).

7. Amend § 460.98 by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

* * * * *

8. Amend § 460.112 by revising paragraph (a) to read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

* * * * *

Title 45—Public Welfare

PART 86—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION

PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

9. The authority citation for part 86 is revised to read as follows:

Authority: 20 U.S.C. 1681 -1688; Pub. L. No. 100-259, 102 Stat. 28 (Mar. 22, 1988).

§ 86.2 [Amended]

10. Amend § 86.2:

a. In paragraph (a), by adding “1687, 1688” after “1686”.

b. In paragraph (n), by removing the words “United States Commissioner of Education” and adding in their place the words “Secretary of Education”.

11. Add § 86.18 to read as follows:

§ 86.18 Amendments to conform to statutory exemptions.

(a) Nothing in this part shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal Funds to perform or pay for an abortion.

(b) Nothing in this part shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in the preceding sentence shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.

(c) This part shall be construed consistently with, as applicable, the First Amendment to the Constitution, Title IX's religious exemptions (20 U.S.C. 1681(a)(3) and 1687(4)), the Religious Freedom Restoration Act (42 U.S.C. 2000b *et seq.*), and provisions related to abortion in the Church Amendments (42 U.S.C. 300a-7), the Coats-Snowe Amendment (42 U.S.C. 238n), Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), and appropriation rider provisions relating to abortion, to the extent they remain in effect or applicable, such as the Hyde Amendment (*e.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115-245, Div. B, sec. 506-507), the Helms Amendment (*e.g.*, Continuing Appropriations Act, 2019, Pub. L. 116-6, Div. F, Titl III), and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115-245, Div. B, sec. 507(d)).

12. Amend § 86.31 by revising paragraph (b) to read as follows:

§ 86.31 Education programs or activities.

* * * * *

(b) *Specific prohibitions.* Except as provided in this subsection, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-State fees and tuition;

(6) Aid or perpetuate 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;

(7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

* * * * *

13. Revise § 86.71 to read as follows:

§ 86.71 Enforcement procedures.

For the purposes of implementing this Part, the procedural provisions applicable to Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby

adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

14. Revise part 92 to read as follows:

NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OR BY ENTITIES ESTABLISHED UNDER SUCH TITLE

Subpart A—General Provisions

Sec.

- 92.1 Purpose.
- 92.2 Nondiscrimination requirements.
- 92.3 Scope of application.
- 92.4 Assurances.
- 92.5 Enforcement mechanisms.
- 92.6 Relationship to other laws.

Subpart B—Specific Applications to Health Programs or Activities

- 92.101 Meaningful access for individuals with limited English proficiency.
- 92.102 Effective communication for individuals with disabilities.
- 92.103 Accessibility standards for buildings and facilities.
- 92.104 Accessibility of information and communication technology.
- 92.105 Requirement to make reasonable modifications.

Authority: 42 U.S.C. 18116; 5 U.S.C. 301, Pub. L. No. 100-259, 102 Stat. 28 (Mar. 22 1988); 42 U.S.C. 2000d *et seq.* (Title VI of the Civil Rights Act of 1964, as amended); 29 U.S.C. 794 (Section 504 of the Rehabilitation Act of 1973, as amended); 20 U.S.C. 1681 *et seq.* (Title IX of the Education Amendments of 1972, as

amended); 42 U.S.C. 6101 *et seq.*; (Age Discrimination Act of 1975, as amended); *Lau v. Nichols*, 414 U.S. 563 (1974).

§ 92.1 Purpose.

The purpose of this part is to provide for the enforcement of Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, prohibiting discrimination under any health program or activity receiving Federal financial assistance, or under any program or activity administered by an Executive agency, or by any entity established, under Title I of such law, on the grounds of race, color, national origin, sex, age, or disability, except as provided in Title I of such law (or any amendment thereto). Section 1557 requires the application of the enforcement mechanisms under 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.*), and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) for purposes of violations of Section 1557 and this part.

§ 92.2 Nondiscrimination requirements.

(a) Except as provided in Title I of the Patient Protection and Affordable Care Act (or any amendment thereto), an individual shall not, on any of the grounds set forth in paragraph (b) of this section, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the U.S. Department of Health and Human Services; or under any program or activity administered by the

Department under such Title; or under any program or activity administered by any entity established under such Title.

(b) The grounds are the grounds prohibited under the following statutes:

(1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (race, color, national origin);

(2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (sex);

(3) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) (age); or

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (disability).

§ 92.3 Scope of application.

(a) Except as otherwise provided in this part, this part applies to

(1) Any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department;

(2) Any program or activity administered by the Department under Title I of the Patient Protection and Affordable Care Act; or

(3) Any program or activity administered by any entity established under such Title.

(b) As used in this part, “health program or activity” encompasses all of the operations of entities principally engaged in the business of providing health care that receive Federal financial assistance as described in paragraph (a)(1) of this section. For any entity not principally engaged in the business of providing health care, the requirements applicable to a “health program or activity” under this part

shall apply to such entity's operations only to the extent any such operation receives Federal financial assistance as described in paragraph (a)(1) of this section.

(c) For purposes of this part, an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing health care.

§ 92.4 Assurances.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the entity's health programs or activities will be operated in compliance with Section 1557 and this part. A health insurance issuer seeking certification to participate in an Exchange or a State seeking approval to operate a State Exchange to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the health program or activity will be operated in compliance with Section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing Section 504 at 45 CFR 84.5(b).

(c) *Covenants*. When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing Section 504 at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under Section 1557 and this part.

§ 92.5 Enforcement mechanisms.

(a) The enforcement mechanisms provided for, and available under, 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.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), including under the Department's regulations implementing those statutes, shall apply for purposes of violations of § 92.2 of this part.

(b) The Director of the Office for Civil Rights has been delegated the authority to enforce 42 U.S.C. 18116 and this part, which includes the authority to handle complaints, initiate and conduct compliance reviews, conduct investigations, supervise and coordinate compliance within the Department, make enforcement referrals to the Department of Justice, in coordination with the Office of the General Counsel and the relevant component or components of the Department, and take other appropriate remedial action as the Director deems necessary, in coordination with the relevant component or components of the Department, and as allowed by law to overcome the effects of violations of 42 U.S.C. 18116 or of this part.

§ 92.6 Relationship to other laws.

(a) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under 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.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2 of this part.

(b) Insofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided by 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.*), 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), the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115-245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)), or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

Subpart B—Specific Applications to Health Programs or Activities

§ 92.101 Meaningful access for individuals with limited English proficiency.

(a) *Obligation.* Any entity operating or administering a health program or activity subject to this part shall take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals.

(b) *Specific applications—(1) Enforcement discretion.* In evaluating whether any entity to which paragraph (a) of this section applies has complied with paragraph (a) of this section, the Director of the Department's Office for Civil Rights may assess how such entity balances the following four factors:

(i) The number or proportion of limited English proficient individuals eligible to be served or likely to be encountered in the eligible service population;

(ii) The frequency with which LEP individuals come in contact with the entity's health program, activity, or service;

(iii) The nature and importance of the entity's health program, activity, or service; and

(iv) The resources available to the entity and costs.

(2) *Language assistance services requirements.* Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of language assistance services, such services must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. Language assistance services may include:

(i) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an

individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency; and

(ii) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English.

(3) *Specific requirements for interpreter and translation services.* (i) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of interpreter services, they must be provided by an interpreter who:

(A) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(C) Is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(ii) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of translation services for written content (in paper or electronic form), they must be provided by a translator who:

(A) Adheres to generally accepted translator ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in writing and understanding at least written English and the written language in need of translation; and

(C) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(iii) If remote audio interpreting services are required to comply with paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, the entity to which Section 1557 applies (as defined in § 92.3 of this part) shall provide:

(A) Real-time, audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(B) A clear, audible transmission of voices; and

(C) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the remote interpreting services.

(4) *Restricted use of certain persons to interpret or facilitate communication.* If an entity is required by paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, to provide interpretation services, such entity shall not:

(i) Require an individual with limited English proficiency to provide his or her own interpreter;

(ii) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except

(A) In an emergency involving an imminent threat to the safety or welfare of an individual or the public, where there is no qualified interpreter for the individual with limited English proficiency immediately available;

(B) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(iii) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public, where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(iv) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(c) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.102 Effective communication for individuals with disabilities.

(a) Any entity operating or administering a program or activity under this part shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs or activities, in accordance with the standards found at 28 CFR 35.160 through 35.164.

Where the regulatory provisions referenced in this section use the term “public entity,” the term “entity” shall apply in its place.

(b) A recipient or State Exchange shall provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(1) Auxiliary aids and services include:

(i) Interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(f); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing; and

(ii) Readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision.

(2) When an entity is required to provide an interpreter under subsection (b), the interpreting service shall be provided to individuals free of charge and in a timely manner, via a remote interpreting service or an onsite appearance, by an interpreter who

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(3) An interpreter for an individual with a disability for purposes of this section can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

(c) Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the Americans with Disabilities Act (ADA), as amended (42 U.S.C. 12102 *et seq.*). Where this part cross-references regulatory provisions that use the term “handicap,” “handicap” means “disability” as defined in this section.

§ 92.103 Accessibility standards for buildings and facilities.

(a) Each 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 shall comply with the 2010 Standards, if the construction or alteration was commenced on or after July 18, 2016, except that if a 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, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards if the construction was commenced after January 18, 2018. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a “public building or facility” as defined in section 106.5 of the 2010 Standards.

(b) Each facility or part of a facility in which health programs or activities under this part are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with the 1991 Standards at appendix D to 28 CFR part 36 or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each 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 in conformance with UFAS shall be deemed to comply

with the requirements of this section and with 45 CFR 84.23(a) and (b), if the construction was commenced before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

(c) For purposes of this part:

(1) “1991 Standards” refers to the 1991 Americans with Disabilities Act Standards for Accessible Design at appendix D to 28 CFR part 36.

(2) “2010 Standards” refers to the 2010 ADA Standards for Accessible Design, as defined in 28 CFR 35.104.

(3) “UFAS” refers to the Uniform Federal Accessibility Standards as promulgated in 49 FR 31528 (Aug. 7, 1984).

§ 92.104 Accessibility of information and communication technology.

(a) Entities required to comply with § 92.2, unless otherwise exempted by this part, shall ensure that their health programs or activities provided through information and communication technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through information and communication technology.

(b) A recipient or State Exchange shall ensure that its health programs or activities provided through websites comply with the requirements of Title II of the Americans with Disabilities Act (42 U.S.C. 12131 through 12165).

(c) For purposes of this part, “information and communication technology” (ICT) means information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and, electronic documents.

§ 92.105 Requirement to make reasonable modifications.

Any entity to which Section 1557 applies (as defined in § 92.3 of this part) shall make reasonable modifications to its policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the regulation promulgated under Title II of the Americans with Disabilities Act, at 28 CFR 35.130(b)(7).

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

15. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 18021, 18031, 18041, 18044, 18054, 18061, 18063, 18071, and 18082, 26 U.S.C. 36B, 31 U.S.C. 9701.

16. Amend § 147.104 by revising paragraph (e) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

Subpart B—GENERAL STANDARDS RELATED TO THE ESTABLISHMENT OF AN EXCHANGE

17. The authority citation for Part 155 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083.

18. Amend § 155.120 by revising paragraph (c)(1)(ii) to read as follows:

§ 155.120 Non-interference with Federal law and non-discrimination standards.

* * * * *

(c) * * *

(1) ***

(ii) Not discriminate based on race, color, national origin, disability, age, or sex.

* * * * *

19. Amend § 155.220 by revising paragraph (j)(2)(i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(j) * * *

(2) * * *

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting HealthCare.gov), coercive, or discriminates based on race, color, national origin, disability, age, or sex;

* * * * *

**PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE
AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES**

20. The authority citation for part 156 continues to read as follows:

Authority: 5 U.S.C. 552; 42 U.S.C. 300jj-11 and 300jj-14.

21. Amend § 156.200 by revising paragraph (e) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.

22. Amend § 156.1230 by revising paragraph (b)(3) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(3) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting HealthCare.gov), coercive, or discriminates based on race, color, national origin, disability, age, or sex.

* * * * *

Dated: May 23, 2019.

Alex M. Azar II

Secretary,

Department of Health and Human Services.

[FR Doc. 2019-11512 Filed: 6/13/2019 8:45 am; Publication Date: 6/14/2019]