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

RIN 0945–AA11

Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (''the Department'' or ''HHS'') 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 (''ACA''). After considering public comments, in this final rule, the Department revises its Section 1557 regulations, Title IX regulations, and specific regulations of the Centers for Medicare & Medicaid Services (''CMS'') as proposed, with minor and primarily technical corrections. This will 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: This rule is effective August 18, 2020.

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

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose

This regulation finalizes the Department's proposed rule concerning Nondiscrimination in Health and Health Education Programs or Activities issued in the **Federal Register** on June 14, 2019 (84 FR 27846), with minor and primarily technical corrections. It makes changes to the Department's existing regulation [1] (''2016 Rule'') implementing Section 1557 of the ACA, 42 U.S.C. 18116. It makes a related amendment to the Department's regulations implementing Title IX of the Education Amendments of 1972 (''Title IX''), and it makes conforming amendments to nondiscrimination provisions within various CMS regulations.

Through Section 1557 of the ACA, 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 ACA or by an entity established under such Title. It did so by cross-referencing statutes that specify prohibited grounds of discrimination, namely, 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.[2]

This final rule returns to the enforcement mechanisms provided for, and available under, those longstanding statutes and the Department's implementing regulations. It eliminates many of the provisions of the 2016 Rule in order to better comply with the mandates of Congress, relieves approximately $2.9 billion in undue regulatory burdens (over five years), furthers substantive compliance, reduces confusion, and clarifies the scope of Section 1557. It empowers the Department to continue its robust enforcement of civil rights laws by making clear that the substantive protections of Title VI of the Civil Rights Act of 1964 (''Title VI''), Title IX, the Age Discrimination Act of 1975 (''Age Act''), and Section 504 of the Rehabilitation Act of 1973 (''Section 504'') remain in full force and effect.[3]

This final rule is needed because the Department has determined that portions of the 2016 Rule are duplicative or confusing, impose substantial unanticipated burdens, or impose burdens that outweigh their anticipated benefits. Additionally, two Federal district courts have determined that the Department exceeded its authority in promulgating parts of the regulation, and one has vacated and remanded those parts of the 2016 Rule. By substantially repealing much of the 2016 Rule, including removing the vacated provisions from the Code of Federal Regulations, the Department reverts to longstanding statutory interpretations that conform to the plain meaning of the underlying civil rights statutes and the United States Government's official position concerning those statutes.

The Department initially estimated the costs from the 2016 Rule at over $942 million across the first five years. 81 FR 31458–59. This figure, however, significantly underestimated actual costs, according to the Department's current estimates. As estimated now, the costs derived merely from the 2016 Rule's requirement to provide notices and taglines with all significant communications, after accounting for electronic delivery, amount to an average annual burden of $585 million per year, for a five-year burden of $2.9 billion. Based on the Department's re-examination of the burden on regulated entities, and after reviewing public comments, the Department has 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.

B. Summary of Major Provisions

(1) Changes to the Section 1557 Regulation

a. Elimination of Overbroad Provisions Related to Sex and Gender Identity

This final rule eliminates certain provisions of the 2016 Rule that exceeded the scope of the authority delegated by Congress in Section 1557. The 2016 Rule's definition of discrimination ''on the basis of sex'' encompassed discrimination on the basis of gender identity (''an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female''). In line with that definition, the 2016 Rule imposed several requirements regarding medical treatment and coverage on the basis of gender identity. The same definition also encompassed discrimination on the basis of ''termination of pregnancy'' without incorporating the explicit abortion-neutrality language of 20 U.S.C. 1688 (which some commenters referred to as the Danforth Amendment) in Title IX, and it imposed a high burden of proof on providers to justify offering gynecological or other single-sex medical services.

All of these are essentially legislative changes that the Department lacked the

[1] 81 FR 31375–473 (May 18, 2016) codified at 45 CFR part 92.

[2] 42 U.S.C. 18116.

[3] While Section 1557 does not incorporate nondiscrimination provisions by reference to Title VII, it provides that nothing in Title I of the ACA 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).

authority to make. They purported to impose additional legal requirements on covered entities that cannot be justified by the text of Title IX, and in fact are in conflict with express exemptions in Title IX, even though Title IX provides the only statutory basis for Section 1557's provision against discrimination ''on the basis of sex.'' For this reason, these provisions have already been vacated and remanded by court order. This final rule omits the vacated language concerning gender identity and termination of pregnancy, thereby bringing the provisions of the Code of Federal Regulations into compliance with the underlying statutes and up-to-date as to the effect of the court's order.

The Department also believes that various policy considerations support this action. The 2016 Rule's provisions on sex discrimination imposed new requirements for care related to gender identity and termination of pregnancy that Congress has never required, and prevented covered entities from drawing reasonable and/or medically indicated distinctions on the basis of sex. As a result, those provisions would have imposed confusing or contradictory demands on providers, interfered inappropriately with their medical judgment, and potentially burdened their consciences. By contrast, under this final rule, each State may balance for itself the various sensitive considerations relating to medical judgment and gender identity, within the limits of applicable Federal statutes (which are to be read according to their plain meaning).

b. Clarification of Scope of Covered Entities

In an additional effort to avoid exceeding the Department's statutory authority, this final rule modifies the 2016 Rule's definition of entities covered by Section 1557 in order to align it more closely with the statutory text.

c. Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement

This final rule also eliminates provisions of the 2016 Rule that, by unnecessarily duplicating or overlapping with existing civil rights law and regulations, were either inconsistent or redundant with existing law and regulations, and so were likely to cause confusion about the rights of individuals and the corresponding responsibilities of providers. This final rule prohibits any covered entity from discriminating on the basis of race, color, national origin, sex, age, and disability, according to the meaning of these terms in the underlying Federal civil rights statutes that Section 1557 incorporates, and it commits the Department to enforcing these prohibitions through the enforcement mechanisms already available under those statutes' respective implementing regulations. It eliminates the 2016 Rule's definitions of terms and its list of examples of discriminatory practices, as well as its provisions related to discrimination on the basis of association, disparate impact on the basis of sex, health insurance coverage, certain employee health benefits programs, notification of beneficiaries' rights under civil rights laws, designation of responsible employees and adoption of grievance procedures, access granted to OCR for review of covered entities' records of compliance, prohibitions on intimidation and retaliation, enforcement procedures, private rights of action, remedial action, and voluntary action. In all of these matters, this final rule will defer to the relevant existing regulations and the relevant case law with respect to each of the underlying civil rights statutes, as applied to the health context under Section 1557. It will not create, as the 2016 Rule did, a new patchwork regulatory framework unique to Section 1557 covered entities.

d. Elimination of Unnecessary Regulatory Burdens

This final rule modifies provisions of the 2016 Rule that imposed regulatory burdens on covered entities greater than what was needed in order to ensure compliance with civil rights law. Specifically, it eliminates the burdensome requirement for covered entities to send notices and taglines with all significant communications, clarifies that the provision of health insurance, as such, is not a ''health program or activity,'' brings requirements of meaningful access for persons with limited English proficiency (LEP) into conformity with longstanding DOJ and HHS guidance, and permits remote English-language interpreting services to be audio-based rather than requiring them to be video-based.

The final rule retains numerous other provisions of the 2016 Rule that furthered the goal of civil rights compliance without imposing burdens unnecessary to that goal. These include the obligation for covered entities to submit assurances of compliance, as well as most of the 2016 Rule's provisions ensuring access for individuals with LEP and individuals with disabilities.

e. Other Clarifications and Minor Modifications

This final rule modifies the 2016 Rule's discussion of its own relation to other laws, offering a clearer commitment to implement Section 1557 in conformity with the text of the statutes it incorporates, as well as with the text of numerous other applicable civil rights and conscience statutes. It also makes other minor modifications to the regulatory text.

(2) Related and Conforming Amendments to Other Regulations

a. Title IX

Because the Department's failure to incorporate the abortion neutrality language at 20 U.S.C. 1688 (hereinafter ''abortion neutrality'') and the Title IX religious exemption formed part of the *Franciscan* court's reasoning when it vacated parts of the 2016 Rule, this final rule amends the Department's Title IX regulations to explicitly incorporate relevant statutory exemptions from Title IX, including abortion neutrality and the religious exemption.

b. CMS

Ten provisions in CMS regulations, all of which cover entities that are also subject to Section 1557, have in recent years had language inserted that prohibits discrimination on the basis of sexual orientation and gender identity. In light of this final rule's return to the plain meaning of ''on the basis of sex'' in the civil rights statutes incorporated under Section 1557, and the overarching applicability of Section 1557 to these programs, the Department here finalizes amendments to those regulations to ensure greater consistency in civil-rights enforcement across the Department's different programs by deleting the provisions on sexual orientation and gender identity.

C. Summary of the Costs and Benefits of the Major Provisions

This final rule is an economically significant deregulatory action. The Department projects that this final rule will result in approximately $2.9 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 2016 Rule's provisions related to mandatory notices. 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 existing regulatory requirements regarding the

establishment of grievance procedures. The Department estimates that there will be some additional costs to covered entities regarding training and revision of policies and procedures.

The Department believes that the anticipated benefits—which include consistency with Federal statutes, 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 changes.

Provision(s)	Savings and benefits	Costs
Sec. 1557: Elimination of Overbroad Provisions Related to Sex and Gender Identity.	For provisions already vacated, eliminating them brings the Code of Federal Regulations in line with current law. For other provisions, eliminating them restores the rule of law by confining regulation within the scope of the Department's legal authority; restores Federalism by leaving to the States decisions properly reserved to them; and removes unjustified burdens on providers' medical judgment.	No costs are anticipated for provisions already vacated, and any possible costs for related provisions are not calculable based on available data.
Sec. 1557: Clarification of Scope of Covered Entities.	Correcting this provision improves the rule of law by interpreting the statute according to its plain meaning as closely as possible.	Costs are not calculable based on available data.
Sec. 1557: Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement.	Eliminating these provisions reduces duplication, inconsistency, and possible confusion in the Department's civil rights regulations, making it easier for covered entities and individuals to know their respective responsibilities and rights.	The Department estimates $275.8 million of costs in the first year for revision of policies and procedures, along with corresponding retraining of employees. (These costs encompass the next listed set of provisions as well.)
Sec. 1557: Elimination of Unnecessary Regulatory Burdens.	Eliminating these provisions reduces unnecessary, unjustified, or excessive burdens on health providers, as well as excessive and confusing paper notices for patients. This will make healthcare more affordable and accessible for Americans and is estimated to save $585 million per year over the first five years.	See above.
Sec. 1557: Other Clarifications and Minor Modifications.	Amending these provisions improves the rule of law by ensuring that regulations remain subject to statutory protections for conscience and other civil rights, and otherwise contributes to the goals of the other regulatory changes listed above.	No costs are anticipated, and any possible costs are not calculable based on available data.
Title IX regulations, related amendment.	This amendment ensures the rule of law by clarifying that Title IX regulations are subject to the statute's own abortion-neutrality language and religious exemption.	No costs are anticipated, and any possible costs are not calculable based on available data.
CMS regulations, conforming amendments.	These amendments restore the rule of law by confining regulations within the scope of their legal authority, and ensure consistency in civil-rights enforcement across the Department's different programs.	Costs are not calculable based on available data.

II. Background

On May 18, 2016, the Department finalized a regulation implementing Section 1557 of the ACA. The Department had received 402 comments [4] in response to a related request for information in 2015, and 24,875 comments [5] in response to the relevant Notice of Proposed Rulemaking, 80 FR 54172–221 (''2015 NPRM'').

Multiple States and private plaintiffs challenged the 2016 Rule in Federal district courts in Texas and North Dakota on the grounds that it violated Federal laws, including the Administrative Procedure Act (''APA'') and the Religious Freedom Restoration Act (''RFRA'').[6] On December 31, 2016, the U.S. District Court for the Northern District of Texas preliminarily enjoined, on a nationwide basis, portions of the 2016 Rule that had interpreted Section 1557 to prohibit discrimination on the basis of gender identity and termination of pregnancy.[7]

On May 2, 2017, the Department of Justice, on behalf of HHS, filed a motion for voluntary remand to reassess the reasonableness, necessity, and efficacy of the enjoined provisions. On May 24, 2019, HHS issued a notice of proposed rulemaking (''the proposed rule'' or ''the 2019 NPRM'') to amend the 2016 Rule, as well as its regulations effectuating Title IX,[8] and to make conforming amendments to certain nondiscrimination provisions of CMS regulations [9] covered by Section 1557. On June 14, 2019, HHS published the proposed rule in the **Federal Register** [10] and accepted public comment for 60 days thereafter.

On October 15, 2019, upon motion of the plaintiffs, and adopting the reasoning from its preliminary injunction order, the U.S. District Court for the Northern District of Texas vacated and remanded the ''the unlawful portions'' of the 2016 Rule that had been subject to that order.[11] On

[4] *https://www.regulations.gov/docket?D=HHS-OCR-2013-0007.* The comment docket identifies 162 submissions, but some submissions to the docket aggregated multiple comments.

[5] *https://www.regulations.gov/docket?D=HHS-OCR-2015-0006.* The comment docket identifies 2,188 submissions, but some submissions to the docket aggregated multiple comments, and ''the great majority'' of comments were not electronic but were submitted by mail as part of ''mass mail campaigns organized by civil rights/advocacy groups.'' 81 FR 31376.

[6] Complaint, *Franciscan All., Inc.* v. *Burwell,* No. 7:16–cv–00108–O (N.D. Tex. Aug. 23, 2016); *Religious Sisters of Mercy* v. *Burwell,* No. 3:16–cv–386 (D.N.D. filed Nov. 7, 2016); *Catholic Benefits Association* v. *Burwell,* No.3:16–cv–432 (D.N.D. filed Dec. 28, 2016).

[7] *See Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016).

[8] 20 U.S.C. 1681 *et seq.;* 45 CFR part 86 (Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance).

[9] 42 CFR 438.3, 438.206, 440.262, 460.98, 460.112; 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230.

[10] 84 FR 27846 (June 14, 2019) (''Nondiscrimination in Health and Health Education Programs'').

[11] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (''Since the Court concludes that ''the Rule's conflict with its incorporated statute—Title IX—renders it contrary to law under the APA,'' the appropriate remedy is *vacatur.* Order 38, ECF No. 62. Accordingly, the Court VACATES and REMANDS the unlawful portions of the Rule for Defendants' further consideration in light of this opinion and the Court's December 31, 2016 Order.''; *id.* at 947 (''The Court ADOPTS its prior reasoning from the

Continued

November 21, 2019, the court clarified that ''the Court vacates only the portions of the Rule that Plaintiffs challenged in this litigation,'' namely, ''insofar as the Rule defines *'On the basis of sex'* to include gender identity and termination of pregnancy . . . The remainder of 45 CFR part 92 remains in effect.'' [12]

The Department herein finalizes the proposed rule without change, except as set forth below, after careful consideration of and responses to public comments.

III. Response to Public Comments on the Proposed Rule

The Department received 198,845 comments in response to the proposed rule during the public comment period.[13] Commenters included Members of Congress, State and local governments, State-based Exchanges, tribes and tribal governments, healthcare providers, health insurers, pharmacies, religious organizations, civil rights groups, non-profit organizations, and individuals, among others.

A. General Comments

Comment: Several commenters, including healthcare providers, explained that although they support nondiscrimination in healthcare and equal access to healthcare for all patients, they have difficulty complying with the parameters of the 2016 Rule. They believe that civil rights protections should be balanced against the burdens they create. Accordingly, these commenters support the proposed regulation as it limits the burdens imposed on providers.

Response: The Department agrees with these commenters' support of nondiscrimination in healthcare and intends to robustly enforce the civil rights authorities. The Department is also cognizant of unduly burdensome regulations. For example, the 2016 Rule did not anticipate some costs to covered entities that range from hundreds of millions to billions of dollars as a result of notice and taglines requirements. Therefore, this final rule seeks to alleviate certain burdens on covered entities while still enforcing the nondiscrimination requirements of Title VI, Title IX, the Age Act, and Section 504.

Comment: Some commenters said the proposed rule would stabilize services for individuals with disabilities and create a more equitable distribution of health services.

Response: The Department agrees. This final rule maintains appropriate protections for individuals with disabilities and will provide clarity for providers and individuals.

Comment: Several commenters expressed concern that eliminating discrimination protections in Section 1557 will cause confusion about patients' rights and remove access to administrative remedies that were previously available.

Response: The Department recommits itself in this rule to enforcing nondiscrimination on the basis of all categories protected by statute. The Department is confident that the clarity associated with maintaining longstanding prohibitions on discrimination under Title VI, Title IX, the Age Act, and Section 504, and their respective implementing regulations, will outweigh any initial confusion stemming from the change.

Comment: Some commenters noted the extensive process involved in developing the 2016 Rule, which included a request for information, the 2015 NPRM, and the 2016 Rule, with the Department considering more than 24,875 public comments. Such commenters suggested this proposed rule unnecessarily reopens the 2016 Rule and ignores the reasoned process that the Department had previously completed. Also, a commenter asked why the Department did not publish a request for information before the proposed rule. Others stated that the proposed rule relies disproportionately on a single district court case, *Franciscan Alliance,*[14] to justify a new interpretation of sex. The commenters go on to suggest that the Department relied exclusively on *Franciscan Alliance* to open up the entire 2016 Rule for edits while ignoring numerous other court cases that come to opposing conclusions regarding sex discrimination.[15]

Response: On December 31, 2016, the *Franciscan Alliance* court preliminarily enjoined the 2016 Rule's gender identity and termination of pregnancy provisions on a nationwide basis, finding them unlawful under the APA and RFRA. A few weeks later, a second Federal district court preliminarily stayed enforcement of the 2016 Rule against two other plaintiffs, citing the *Franciscan* decision.[16] Because of the nationwide preliminary injunction, the Department could not enforce certain provisions from the 2016 Rule. In the process of reconsidering the 2016 Rule, and consistent with applicable Executive Orders and deregulatory priorities, the Department examined the rule more broadly and concluded that, for the reasons explained in the 2019 NPRM, the 2016 Rule had significantly underestimated the costs and burdens it imposed. Because Section 1557 authorizes, but does not require, the creation of new implementing regulations, the Department considered it appropriate to repeal certain portions of the 2016 Rule and enforce Section 1557 using the underlying regulations the Department has used to enforce the relevant civil rights statutes identified in Section 1557. The Department also considered the Executive Branch's most recent statements concerning the interpretation of statutory provisions that prohibit discrimination on the basis of sex.

The Department published its proposed rule in the **Federal Register** on June 14, 2019, opening a two-month public comment period. The Department received nearly 200,000 comments for its review. Through this public comment period, the public was given a full opportunity to provide the Department with information regarding the proposal. It is not necessary to engage in an additional solicitation of public comments through a request for information before the notice of proposed rulemaking. The Department also reviewed the 2016 Rule record and its public comments in considering this final rule.

Through this rulemaking, the Department has provided a comprehensive rationale for this final rule. The 2019 NPRM summarized the Department's legal authority to change the 2016 Rule along with policy rationales for doing so. The quantum of evidence necessary to justify rescinding provisions of a rule is not greater than the evidence needed for issuing it in the

preliminary injunction (ECF No. 62) and now HOLDS that the Rule violates the APA and RFRA. Accordingly, the Court VACATES and REMANDS the Rule for further consideration.'').

[12] Order, *Franciscan Alliance,* No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

[13] *See https://www.regulations.gov/docket?D=HHS-OCR-2019-0007.* The comment docket identifies 155,966 submissions, but some submissions to the docket aggregated multiple comments. HHS estimates the disaggregated number of comments to be 198,845.

[14] *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016).

[15] Commenters cited *Boyden* v. *Conlin,* 341 F. Supp. 3d 979 (W.D. Wisc. 2018) (holding Wisconsin's use of transgender exclusions in its state employee health insurance plan constituted sex discrimination in violation of Section 1557 and Title VII); *Flack* v. *Wis. Dept. of Health Servs.,* 328 F. Supp. 3d 931, 951 (W.D. Wis. 2018); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (finding Section 1557's plain language bars gender identity discrimination); *Tovar* v. *Essential Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (same).

[16] *Religious Sisters of Mercy* v. *Burwell,* Nos. 3:16–cv–386 & 3:16–cv–432 (D.N.D. Order of January 23, 2017). *See* 84 FR 27848.

first place.[17] Moreover, after publication of the proposed rule, the Court in *Franciscan Alliance* issued its final judgment vacating and remanding the unlawful portions of the 2016 Rule for the Department's further consideration. The Department has considered that *vacatur,* along with the legal authorities and policy rationales discussed in the NPRM and this preamble, and more thoroughly calculated the costs and effects of the notice and taglines requirements, to arrive at this final rule. Specific responses to comments on its various provisions, including on sex discrimination, are found below.

Comment: Some commenters expressed concern that the updated Section 1557 regulations will have unintended consequences and costs for healthcare providers and individuals seeking healthcare and insurance, particularly pertaining to access standards for people with LEP and communication-based disabilities, in part because the regulatory drafting period was shorter than the period for the 2016 Rule.

Response: The Department has spent several months carefully reviewing comments, providing responses to them in this rule, and finalizing the proposed rule. The Department is leaving several substantive provisions of the 2016 Rule unchanged or substantially unchanged. The changes largely consist of excisions of regulatory text as opposed to the addition of new text, so it is unsurprising that the regulatory drafting period was shorter than the period for the 2016 Rule. In many instances where new or modified regulatory text was proposed, such text was based on existing guidance or regulatory text. The Department considers this to be an adequate process and a sufficient period of time to engage in such rulemaking.

This final rule maintains vigorous protections for people with LEP and communication-based disabilities, as discussed in detail below, and the Department intends to continue robust enforcement of those protections.

Comment: Several commenters indicated that the cost savings cited in the proposed rule are unsupported or based on insufficient data. Several commenters also contend that the proposed rule ignores the costs to individuals, especially LEP individuals, who will allegedly encounter additional barriers to accessing healthcare as a result of the proposed changes. Some commenters were concerned that the proposed rule would help eliminate access to a wide range of affordable preventive health services, including cancer screenings, contraception, and reproductive health services. The commenters believe this loss of access will largely be caused by the proposed changes to the definition of sex discrimination. Many commenters expressed concern that the proposed rule would remove civil rights protections for a number of vulnerable groups, including LEP individuals, LGBT individuals, individuals with disabilities, and women seeking reproductive healthcare. Such commenters state that the removal of these protections would, in turn, result in even greater health disparities for these vulnerable populations. Some commenters stated that the proposed rule would lead to increased discrimination in healthcare, which would lead people to delay or forego healthcare and would result in adverse health outcomes and greater overall healthcare costs to individuals. Some of these commenters note that based on these anticipated increased disparities, the proposed rule is effectively encouraging discrimination.

Response: This final rule leaves in place all statutory civil rights protections for vulnerable groups. Cost savings are treated in the Regulatory Impact Analysis below, which discusses the data, estimates, and assumptions used to support its calculations. Potential health disparities or other alleged costs to individuals or vulnerable groups, including those due to discrimination or barriers to access, are discussed in the relevant sections below (*e.g.,* potential costs to LEP individuals are discussed in comments on those sections of the regulation that deal with national-origin discrimination and/or LEP, while potential costs relating to the gender identity provision are discussed in comments on the section regarding ''discrimination on the basis of sex'').

Comment: Many commenters expressed their belief that this proposed rule diverges from the current body of civil rights laws. These commenters believe that limiting protections based on gender identity, termination of pregnancy, and LEP, runs contrary to civil rights protections.

Response: Current civil rights laws and their protections are discussed, respectively, in the relevant sections below (*e.g.,* civil rights law on gender identity is discussed in the section on ''discrimination on the basis of sex,'' because the 2016 Rule had classified gender identity discrimination as a form of sex-based discrimination).

Comment: Some commenters stated that civil rights protections should not be eliminated because of compliance costs faced by covered entities, and that such balancing runs contrary to the Affordable Care Act and the Administrative Procedure Act. Such commenters argue that if the Department determines that particular protections are too costly or onerous, it should advance more limited protections rather than eliminating them entirely.

Response: This final rule does not, and could not, repeal or eliminate specific protections under any of the four civil rights statutes referenced in Section 1557, and it does not remove the protections provided by the implementing regulations for those statutes.

The Department has, however, chosen to reduce some excessive burdens that were applied to covered entities by the 2016 Rule, but were not required by Section 1557, where the relevant civil rights protections could be enforced using the underlying regulations without the unnecessary burdens imposed by the 2016 Rule.

Comment: Commenters stated that the Department exceeded its authority by proposing this rule. Some commenters indicated that the Department's positions as advanced in the proposed rule are not worthy of deference under the framework established in *Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984), because the proposed rule is contrary to clear congressional intent and is inconsistent with the agency's past policies concerning sex protections. Many of these commenters assert that the changes set forth in the proposed rule run contrary to the requirements of the ACA, pointing to 42 U.S.C. 18114 (Section 1554), which states that the Department shall not ''promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services. . .'' These commenters also state that the Department is attempting to make a legislative change through an administrative action. Some commenters contend that the proposed rule runs contrary to the general intent of the ACA, namely that all individuals should be provided access to healthcare.

Response: The 2016 Rule tried to make essentially legislative changes through administrative action, and those changes were rightly held to be in violation of the APA. The Department does not exceed its authority by rescinding the portions of the 2016 Rule that exceeded the Department's authority. The Department also does not

[17] *See* 84 FR 27850; *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 514–15 (2009).

violate Section 1554 of the ACA by not including the gender identity and termination of pregnancy provisions in this final rule, which were not supported by the text of the underlying civil rights laws incorporated in Section 1557, and in addition were vacated by court order.

With respect to both Sections 1554 and 1557, the Department interprets the ACA by the plain meaning of its text, and as will be shown below, this final rule brings the Department's Section 1557 regulations in line with a proper understanding of the ACA's text. Parts of the 2016 Rule exceeded the Department's authority under the ACA, and this final rule formally eliminates those portions from the Code of Federal Regulations. The Department believes this approach adheres more closely to the text of the statutes referenced in Section 1557, along with the regulations that the Department has used to implement those statutes for decades. Other parts of the 2016 Rule are being modified or repealed in order to save providers from unnecessary burdens not required by the ACA, so that they are better able to achieve the statute's goal of providing healthcare access to all Americans. Such a reconsideration and elimination of certain regulatory provisions, particularly regulations that the ACA itself did not require to be issued, neither ''creates'' unreasonable regulatory barriers nor impedes timely access to healthcare. If it were otherwise, Section 1554 would essentially serve as a one-way ratchet, preventing the Department from ever reconsidering a regulation that could be characterized as improving access to healthcare in some sense, regardless of the other burdens such regulation may impose on access to health care. The Department's approach in this final rule is also consistent with the Ninth Circuit's recent interpretation of Section 1554: ''[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients.'' [18] As explained throughout the preamble, the Department's rule avoids precisely such burdens by bringing the section 1557 regulations into alignment with the longstanding requirements of the applicable civil rights laws and their implementing regulations (thereby also avoiding additional conscience burdens that the 2016 Rule potentially imposed) and by removing notice and taglines requirements that imposed unjustified burdens on the healthcare system as a whole (some of which would likely have been passed on to individuals).

Comment: Commenters said that Section 1557 should be construed broadly because throughout the ACA, Congress prohibited a variety of forms of discrimination, such as against pre-existing conditions and combating health disparities. Commenters also indicated that the ACA is intended to reduce the cost of healthcare discrimination against the poor, so the Section 1557 rule should implement cost sharing and other insurance requirements.

Response: In the ACA, Congress labeled several provisions other than 1557 as prohibiting discrimination [19] in healthcare, but did not incorporate those other provisions of the ACA into Section 1557. Those other provisions are different from the civil rights provisions set forth in Section 1557 in substance, implementation, and enforcement. This final rule commits the Department to robust enforcement of the nondiscrimination grounds applicable under Section 1557.

Comment: A commenter contended that the Department provided little or no legal, policy, or cost-benefit analysis along with the proposed rule and combined too many changes into a single rule. Some commenters claimed the proposed rule is arbitrary, capricious, and contrary to law, is inconsistent with the agency's mission, and lacks reasoned explanations justifying the policy reversals. Other commenters stated that HHS failed to account for the extensive history of healthcare discrimination, and provided no contrary data to counter the original factual findings in the 2016 Rule. Furthermore, they said that individuals have reasonably placed their reliance upon the Federal government to protect their civil rights as explained in the 2016 Rule.

Response: The Department provided ample legal, policy, and cost-benefit analysis for the proposed rule and provides additional support here for the final rule.[20] The Department proposed changes to the provisions of the 2016 Rule because that rule exceeded the Department's authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, imposed unjustified and unnecessary costs, and conflicted with applicable court decisions. It is unfortunate that, by administrative action, the 2016 Rule may have unreasonably raised expectations about nondiscrimination protections that are not found in the underlying statutes, but this final rule cannot be held responsible for that. The Department gave extensive reasons for its changes in the 2019 NPRM, and gives further reasons in response to comments below. The public comment process provided adequate opportunity to present legal, policy, and cost-benefit analyses, all of which were considered in finalizing this rule, as discussed herein.

The Department also updates and discusses the regulatory impact analysis based on comments and data received. While there are still some questions addressed by this final rule where robust data are unavailable, were not found by the Department, or have not been brought to the Department's attention, the Department is allowed to engage in rulemaking even where the impact of a rule change is difficult or impossible to quantify. The Department has diligently considered the relevant and significant data of which it is aware.

There is no artificial limit on the number of changes a proposed rule may contain—or on the number of parts in the Code of Federal Regulations that can be addressed in a rulemaking. This final rule contains many fewer changes than the 2016 Rule did, and it substantially streamlines the existing 1557 regulation as opposed to enlarging it. Its inclusion of conforming changes to various CMS regulations still gives the final rule a size and scope that is well within the range of other significant proposed rules.

Comment: Several commentators stated that the proposed rule's language that Title IX and Section 1557 must be ''exercised with respect for State sovereignty'' runs contrary to the Supreme Court's decision that Congress has the authority to prohibit discrimination in commercial activity.

Response: This final rule does not, nor does the Department intend to, remove any protection against State action that Congress has provided by statute. It also does not deny States the ability to provide protections that exceed those required by Federal civil rights law. The reference to State sovereignty simply refers to the Department's intention to protect the States by respecting their sovereignty to the extent that doing so does not infringe on Federal law.

Comment: One commenter noted that, after the 2016 Rule was passed, the

[18] *California* v. *Azar,* No. 19–15974, 2020 WL 878528, at *18 (9th Cir. Feb. 24, 2020 (en banc).

[19] *See, e.g.,* ACA Section 2701 (''discriminatory premium rates''); Section 2716 (''discrimination based on salary''); Section 2705 (''discrimination against individual participants and beneficiaries based on health status''); Section 2716 (''discrimination in favor of highly compensated individuals'').

[20] *See* 45 FR at 27875–88.

Department released resources and educational materials, including fact sheets, to explain the 2016 Rule. The commenter requested that the Department release similar resources and educational materials following the finalization of this rule.

Response: The Department is providing the responses to comments contained in this preamble to clarify issues and answer questions concerning this final rule. Furthermore, the Department continues to be committed to providing resources and educational materials to explain civil rights requirements and to assist covered entities with compliance with civil rights statutes and the regulations thereunder, including this regulation.

B. Section 1557 Regulation, Subpart A: General Requirements and Prohibitions

The Department proposed changes to the Section 1557 rule at 45 CFR part 92 to be composed of Subpart A on general requirements and prohibitions, and Subpart B on specific applications related to disability nondiscrimination and language access.

(1) Proposed Repeal of Definitions in § 92.4 of the 2016 Rule

Comments: A commenter contended that eliminating the definitions section in the Section 1557 Regulation would cause confusion, misinterpretation, and inconsistency of terms among the regulations that currently reference or otherwise rely on the underlying definitions in the 2016 Rule.

Response: In significant part, the definitions section of the 2016 Rule duplicates definitions already incorporated into the Section 1557 regulation by reference, and hence creates either inconsistency or redundancy. In other cases, the 2016 Rule contained definitions inconsistent with the text of applicable statutes; indeed, on those grounds, a Federal district court vacated the 2016 Rule's definition of ''on the basis of sex'' insofar as it encompassed gender identity and termination of pregnancy. The Department will continue to enforce Section 1557 using HHS regulations for the underlying civil rights statutes. Many of these regulations have definition sections and operate based on longstanding understandings of how the laws are enforced.

Comments: Some commenters argued that eliminating the phrases ''covered entities'' and ''health program or activities'' would allow many plans and programs to be exempt from the Section 1557 regulation. Other commenters stated that the existing definitions provide clarity and consistency for covered entities. Another commenter stated that the proposed rule would limit Section 1557's application to the specific program or activity that receives Federal assistance, rather than a healthcare entity's entire operations.

Response: See below, under ''Scope of Application in Proposed § 92.3,'' for a discussion of the entities subject to this final rule.

Comment: Some commenters asked the Department to retain the definition of ''auxiliary aids and services'' concerning effective communication for individuals with disabilities. They also asserted that the Department has altered important definitions related to effective communication, without explanation or acknowledgement. While some commenters appreciated the Department's efforts to incorporate many of the current definitions of Title II of the Americans with Disabilities Act[21] (''ADA''), some claim the Department has erred in tracking the language of those definitions.

Response: The Department is not required to track ADA definitions in its Section 1557 regulation. This final rule applies many definitions based on those found in the ADA or its regulations (including ''disability'' and ''auxiliary aids and services''), technical definitions and standards under the ADA, and Uniform Federal Accessibility Standards as promulgated; as discussed below, it also departs from ADA definitions in certain cases. Additionally, this final rule retains effective communication standards for individuals with disabilities under § 92.102; these provisions are drawn from regulations promulgated by the Department of Justice implementing Title II of the ADA.[22] Specific definitions and provisions related to individuals with disabilities are discussed below.

The proposed rule apprised the public of the language the Department sought to finalize in the rule, gave the Department's reasons for changes relative to the 2016 Rule, and provided an opportunity to comment on the proposed language.

Comment: Some commenters opposed the proposed removal of the definition for ''national origin,'' saying it would lead to confusion among providers and recipients as to what constitutes discrimination on the basis of national origin.

Response: The term ''national origin'' is not specifically defined in Title VI or in HHS's implementing regulation, but the Department has appropriately enforced the prohibition on national origin discrimination under Title VI for decades in accord with relevant case law. In implementing this final rule, the Department intends to enforce vigorously the prohibition on national origin discrimination in a manner consistent with the current interpretation under Title VI, including under *Lau* v. *Nichols,* as discussed below.[23]

Comment: Some commenters asserted that the removal of definitions weakens protections for LEP individuals and signals a lack of priority for enforcement by the Department.

Response: As discussed below, meaningful access for individuals with LEP is a key component of the national origin protections under Title VI and Section 1557, and will be well protected by this final rule. The streamlining of this regulation through the elimination of largely redundant definitions will in no way impede the Department's strong commitment to meaningful access for LEP individuals.

Summary of Regulatory Changes: The Department finalizes its repeal of § 92.4 of the 2016 Rule without change. Additional comments concerning the definitions of sex, gender identity, and other specific definitions are discussed in more detail below.

(2) General Changes to 2016 Rule

a. Purpose of Regulation, Revising § 92.1 of the 2016 Rule

The Department proposed to revise the statement of the purpose of the regulation in § 92.1 from ''implement[ation]'' of Section 1557 to ''provid[ing] for the enforcement'' of Section 1557. 84 FR at 27861.

Comment: A commenter said this change in language allows the Department to minimize its involvement in ensuring that nondiscrimination protections are effective.

Response: This is the opposite of the Department's intention. This final rule's title and citation to statutory authority already make clear that it is implementing Section 1557. By changing the rule's language from ''implement'' to ''provide for the enforcement of,'' the Department simply means to emphasize, in terms accessible to a lay audience, that it will fully enforce Section 1557 and the underlying nondiscrimination laws as they fall within the jurisdiction of the Department, according to the text of those laws and their implementing regulations.

[21] 42 U.S.C. 12101 *et seq.*

[22] 42 U.S.C. 12311; *see also* 28 CFR 35.160–164.

[23] *Lau* v. *Nichols,* 414 U.S. 563 (1974).

b. Effective Date

The Department proposed that the effective date of the revised regulation be 60 days after publication of the final rule, in order to relieve significant regulatory burdens, particularly the taglines requirements.[24] The 2016 Rule's effective date was July 18, 2016 (60 days after publication of the final rule), with the exception of the provisions on health insurance and benefit design, which went into effect on January 1, 2017 (the first day of the first plan year following the effective date).[25] The new rule does not include a different effective date for health insurance and benefit design.

Comment: Commenters asked that the Department make the effective date several months prior to the plan open enrollment period that occurs between November 1 and December 15, in order for the covered entities to have sufficient time to incorporate the regulatory changes into the next plan year.

Response: The Department has endeavored to issue this final rule sufficiently in advance of the plan year cycle, so that plans can incorporate the regulatory changes into the next plan year. Moreover, because this final rule generally relieves regulatory requirements rather than adding them, it should be easier for issuers to incorporate such changes into the plans they will offer for the next plan year.

Comment: Commenters stated that it is inappropriate to finalize the change to the definition of sex as it relates to Section 1557 in light of current litigation before the Supreme Court, which may be resolved by the end of the court's term or before. These commenters note that the Supreme Court's ruling in *R.G. & G.R. Harris Funeral Homes* v. *EEOC & Aimee Stephens*[26] will determine whether Title VII of the Civil Rights Act of 1964 extends sex discrimination protections to transgender status, and that the ruling may apply to the definition of sex under Title IX as well. Accordingly, these commenters urge the Department to wait until the Supreme Court decides *Harris Funeral Homes* before publishing a rule that deals with the same subject matter, or allow for commenters to comment again once the case has been decided.

Response: The Department acknowledges the commenters' point of view but respectfully disagrees. The U.S. government has taken the position in *Harris* and other relevant litigation that discrimination ''on the basis of sex'' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity.[27] The Department shares that position and is permitted to issue regulations on the basis of the statutory text and its best understanding of the law and need not delay a rule based on speculation as to what the Supreme Court might say about a case dealing with related issues. The Department also agrees with the *Franciscan Alliance* ruling, according to which the 2016 Rule's extension of sex-discrimination protections to encompass gender identity was contrary to the text of Title IX and hence not entitled to *Chevron* deference.[28] Moreover, to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction.

The Department continues to expect that a holding by the U.S. Supreme Court on the meaning of ''on the basis of sex'' under Title VII will likely have ramifications for the definition of ''on the basis of sex'' under Title IX.[29] Title VII case law has often informed Title IX case law with respect to the meaning of discrimination ''on the basis of sex,''[30] and the reasons why ''on the basis of sex'' (or ''because of sex,'' as used in Title VII) does not encompass sexual orientation or gender identity under Title VII have similar force for the interpretation of Title IX. At the same time, as explained below, the binary biological character of sex (which is ultimately grounded in genetics) takes on special importance in the health context. Those implications might not be fully addressed by future Title VII rulings even if courts were to deem the categories of sexual orientation or gender identity to be encompassed by the prohibition on sex discrimination in Title VII. As a result, the Department considers it appropriate to finalize this rule, which does not define sex, but relies on the plain meaning of the term under Title IX, and does so in the health context within which the Department applies Title IX under Section 1557.

Comment: Commenters disagreed with the Department's reliance on the litigation and court order in *Franciscan Alliance* to justify revisiting the rule, because the injunctive order was not permanent, was allegedly limited to enforcement actions of HHS, and does not require new rulemaking, and because other litigants have intervened in the case to defend the 2016 Rule. Some commenters stated that although the U.S. District Court in *Franciscan Alliance* ruled against the 2016 Rule's definition of sex, other courts have come to conclusions that suggest the opposite, and HHS is not required to alter Department-wide policy based on the injunction in *Franciscan Alliance.* Others argued that the Department improperly relied on one legal decision that they said conflicts with the clear weight of case law. Another commenter stated it would be inappropriate to publish any new rule before a final ruling in *Franciscan Alliance,* as the case is being appealed.

Response: Nearly three years after the preliminary injunction, and after the comment period on the proposed rule had concluded, the court in *Franciscan Alliance* issued a final ruling vacating the 2016 Rule ''insofar as the Rule defines *'On the basis of sex'* to include gender identity and termination of pregnancy,'' and remanding the Rule for further consideration.[31] This final ruling is binding on the Department despite the appellate proceedings still pending in that case: The Department's Section 1557 regulation, as currently operative, does not contain the 2016 Rule's definition of ''on the basis of sex'' to encompass gender identity and termination of pregnancy. The *Franciscan Alliance* court's 2016 injunction gave the Department good cause to reconsider the 2016 Rule, but neither the injunction nor the *vacatur* was the Department's only reason for revising it, as the proposed rule made clear and as the Department's responses to comments in this preamble reiterate. Nothing in the appellate litigation prohibits the Department from finalizing this rule, which it does for the reasons given in this preamble. As for the weight of case law, it is discussed below with respect to the respective provisions of this final rule.

Comment: One commenter noted that the Department's announcement of the proposed rule on May 24, 2019 had stated that a fact sheet explaining the changes in the proposed rule would be

[24] 84 FR at 27888.

[25] 81 FR at 31378.

[26] *R.G. & G.R. Harris Funeral Homes, Inc.* v. *E.E.O.C.,* 139 S. Ct. 1599 (2019).

[27] As noted elsewhere in this preamble, it has been the consistent position of the federal government that ''on the basis of sex'' under Section 1557 does not encompass sexual orientation, including the decision in the 2016 Rule not to include sexual orientation in the definition of that term. *See* 81 FR at 31390.

[28] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (incorporating its previous ruling at 227 F. Supp. 3d at 685–87).

[29] *See* 84 FR 27855.

[30] *See, e.g., Yusuf* v. *Vassar Coll.,* 35 F.3d 709, 714 (2d Cir. 1994).

[31] Order, *Franciscan Alliance,* No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

provided in Spanish. However, no such fact sheet has been provided. Accordingly, the commenter requested that the comment period be extended until 60 days after the fact sheet is published in Spanish.

Response: The proposed rule itself did not purport to offer information in Spanish, and the Department was not under a legal obligation to offer a separate fact sheet or to translate it. The Department's press release indicated that a fact sheet, separately created in connection with the press release, would be translated. That is not a basis for reopening the comment period on the proposed rule, because the proposed rule provided the public with adequate notice and a 60-day public comment period, which were legally sufficient.

c. Severability

The Department proposed to repeal the provision in § 92.2(c) of the 2016 Rule stating that if a regulatory provision in this part were held invalid or unenforceable on its face or as applied to a specific person or circumstances, the provision should be construed to the maximum effect permissible by law and be severable such that it would not affect other persons or circumstances that are dissimilar.

Comment: Commenters asked the Department to add a severability provision to the final rule. Specific points recommended included severing repeal of the provisions related to the notices and taglines, and/or the changed scope of applicability, from the sex discrimination provisions. Commenters said that the Supreme Court case *K-Mart Corp.* v. *Cartier, Inc.,* 108 S. Ct. 1811 (1988), would allow the Department to sever the changes in the taglines provision from the proposed rule and implement those changes even in the event that a court delays or suspends the proposed rule.

Response: In part due to these comments, the Department has decided not to finalize the proposal to eliminate the severability provision from the 2016 Rule. Instead the Department will retain that severability provision, but has moved it to § 92.3(d), because § 92.3 is now the provision addressing the application of the rule. This change will be discussed again below in the discussion of § 92.3.

d. Summary of Regulatory Changes

For the reasons described in the proposed rule, and having considered the comments received, the Department finalizes the proposed § 92.1 without change, and confirms that the effective date of this final rule will be 60 days after its publication in the **Federal Register**.

(3) Scope of Application in Proposed § 92.3; Repeal of § 92.208

The Department proposed to repeal § 92.2 of the 2016 Rule, and instead address the scope of application of Section 1557 in a new § 92.3. 84 FR at 27862–63. The Department also proposed to repeal § 92.208 of the 2016 Rule, which had expanded the scope of the Section 1557 statutory provision to apply to certain employee health benefits programs.[32]

a. Generally

Comment: Commenters argued the Department did not provide a reasoned legal, policy, or cost-benefit analysis to support the repeal of § 92.208, which hindered their ability to provide meaningful comments as required by the APA. The commenters maintained that the Department's comparison of § 92.208 to Title IX [33] was flawed, in part because HHS's Title IX regulation does not apply to all bases of discrimination or many of the same covered entities as addressed under Section 1557. Some commenters noted that employees deserve protection from discrimination in employer-sponsored plans.

Response: As seen below in the response to a similar comment on § 92.207, § 92.208 appears in the NPRM in a list of sections of the 2016 Rule that ''are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations.'' [34] The Department repeals § 92.208 for reasons similar to those given at greater length below in discussing § 92.207: It seeks to relieve regulatory burden and possible confusion by enforcing the relevant nondiscrimination statutes through their existing regulations.

The Department is not aware of data and methods available to make reliable estimates of all economic impacts predicted by various commenters. The Department's estimates of regulatory impact are discussed below.

Comment: Commenters stated that individuals protected by Section 1557, particularly individuals with disabilities, frequently experience discrimination in healthcare. Commenters expressed concerns that the narrowed application would reduce the number of covered entities and would lead to more discrimination, lack of care, and adverse health outcomes, which they argued is contrary to the stated Congressional intent and purpose of the ACA to expand access to and end discrimination in health insurance. Several State and local government commenters expressed concern that the proposed rule would negatively affect public health in their States and increase costs to States due to more people seeking care through government-funded programs, such as Medicaid.

Conversely, other commenters were supportive of the proposed rule's revised scope and agreed that the 2016 Rule was far too broad in its application. They concurred that narrowing the scope of application would help rein in the regulatory excess and burden of the 2016 rule.

Response: The Department must follow the text of the ACA. To the extent that Congressional intent and purpose are relevant, they are best determined by looking to the plain meaning of the statutory text. This final rule will enforce Section 1557's discrimination requirements against the entities that Congress intended them to be enforced against. The Department's specific reasoning in interpreting Section 1557's scope of coverage follows.

b. § 92.3(a): Covered Programs and Activities

The Department proposed in § 92.3(a) that, except as otherwise provided in part 92, the Section 1557 rule will apply 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 ACA; or (3) any program or activity administered by any entity established under Title I of the ACA.

Comment: Some commenters opposed removing the full definition of ''Federal financial assistance'' from the 2016 Rule and replacing it with the limited text under proposed § 92.3(a)(1). They stated that the lack of specificity could lead to ambiguity and confusion. Commenters further asserted that the proposed rule was inconsistent with the Department's recently promulgated *Protecting Statutory Conscience Rights in Health*

[32] *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. The enforcement Memorandum of Understanding (MOU) between OPM and the Department, signed by OCR on 11 January 2017, is moot upon publication of this final rule.

[33] 84 FR at 27869, n.148 (comparing § 92.208 with 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX)).

[34] 84 FR 27869.

Care (''2019 Conscience Rule''),[35] which included an expansive definition of ''Federal financial assistance.'' [36]

Response: The Department concludes it is appropriate to have a definition of Federal financial assistance that mirrors Section 1557's statutory text to include ''credits, subsidies, or contracts of insurance.'' In addition, the definitions applicable under the preexisting civil rights statutes still apply, and the Department believes it is more appropriate to apply those existing definitions than to maintain the ones in the 2016 Rule. Section 1557 says the enforcement mechanisms provided for and available under the underlying civil rights statutes shall apply, and the Department believes operating under those mechanisms and the definitions that have long been applicable to them, along with the language the Department retains in this final rule, is appropriate moving forward. The 2019 Conscience Rule was based on different statutes.

Comment: Some commenters opposed the proposed rule's exclusion of Federal financial assistance that the Department ''plays a role'' in providing or administering, which had been included in the 2016 Rule's definition of Federal financial assistance. Commenters argued that the statute applies to programs or activities administered by ''an Executive Agency'' and thus should not be limited to HHS. In particular, they objected to the result that qualified health plans (QHPs) would no longer be covered under the rule on the basis that HHS plays a role in administering tax credits. The commenters argued that this interpretation is contrary to a plain reading of the statute, which not only uses the broad term ''Federal financial assistance'' (without a modifier to limit it to assistance directly administered by HHS), but also expressly includes ''credits'' as part of Federal financial assistance. Further, some commenters noted that the Department took an inconsistent and broader approach in its Conscience Rule, wherein HHS exerts jurisdiction over statutes and funding also administered by the U.S. Departments of Labor and Education.

Response: The statutory text of Section 1557 refers simply to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.'' Because the Section 1557 regulation applies only to the Department, the 2015 NPRM had reasonably sought to limit its scope to Federal financial assistance from the Department, leaving other Departments to enforce Section 1557 within their own sphere.[37] In the 2016 Rule, however, wishing to encompass tax credits administered under Title I, the Department expanded the rule's scope to encompass ''Federal financial assistance that the Department plays a role in providing or administering.'' [38] The Department now regards this expansion as overbroad. While Section 1557 still applies to any health program or activity receiving any Federal financial assistance, this final rule prescribes enforcement only by the Department and within the Department's jurisdiction. The Department does not consider it appropriate in this final rule to apply its provisions to any programs that the Department ''plays a role in'' administering.

Commenters' concerns about covering QHPs are misplaced: These plans remain subject to this rule because they are sold on the Exchanges established under Title I of the ACA (see § 92.3(a)(3) of this final rule). This final rule only prescribes enforcement of Section 1557 by the Department and within the Department's jurisdiction, so the Department believes it is appropriate for this regulation to not include activities funded or administered solely by other Federal agencies even if Section 1557 may apply in those instances.

The 2019 Conscience Rule (as stated above) relied on different statutes than the Section 1557 rule, and the Department drafts its regulations as appropriate for the underlying statutes.

Comment: Commenters disapproved of proposed § 92.3(a)(2), which would limit the rule's application in the context of HHS-administered programs or activities to only those administered under Title I of the ACA. Commenters argued that this interpretation is inconsistent with the statutory text of Section 1557, which applies to ''any program or activity administered by an Executive Agency *or* any entity established under this title [*sc.,* Title I].'' (emphasis added). Commenters argued the proposed § 92.3(a)(2) would incorrectly apply ''under this title'' to modify both phrases. Furthermore, they argued that the Department did not provide an adequate rationale for its interpretation in the proposed rule.

Response: As explained in the 2019 NPRM, the statutory text of Section 1557 applies to ''any program or activity'' administered by an Executive Agency or Title I entities, but does not include the modifier ''health'' with respect to those programs or activities.[39] In the 2016 Rule, the Department limited its application by adding ''health'' to ''programs or activities'' because the Department recognized that Section 1557 was not intended to apply to every program or activity administered by every Executive Agency, whether or not it related to health.[40] The 2016 Rule acknowledged implicitly what the Department now states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text concerning limits to its scope is less clear than it could have been. In resolving the sentence's ambiguity, however, the Department no longer agrees with the 2016 Rule's decision to add a limiting modifier (*i.e.,* ''health'') that Congress did not include in the statutory text. Instead, the Department concludes that Congress had already placed a limitation in the text of Section 1557 by applying the statute to any program or activity administered by an Executive Agency ''under this title'' (meaning Title I of the ACA), as well as to any program or activity administered by an entity established under such title. The Department believes that either this interpretation of the statutory text, or the 2016 Rule's addition of the modifier ''health,'' is necessary in order to make sense of the statutory text; this final rule offers a technical reading of the text that is at least as reasonable as the 2016 Rule's addition of a word not present in the text of the statute.

Comment: Commenters argued that the proposed interpretation to limit coverage to HHS Title I programs or activities would exclude a number of important programs and activities operated by HHS and is inconsistent with Section 504's application to ''any program or activity conducted by an

[35] *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,* 84 FR 23170–01 (2019).

[36] 45 CFR 88.2.

[37] 80 FR 54173 (''Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal Department. However, this proposed rule would apply only to health programs and activities any part of which receives Federal financial assistance from HHS. This narrowed application is consistent with HHS' enforcement authority over such health programs and activities, but other Federal agencies are encouraged to adopt the standards set forth in this proposed rule in their own enforcement of Section 1557.'').

[38] 81 FR 31467, 31384; *cf.* 80 FR 54216.

[39] 42 U.S.C. 18116(a) (applying Section 1557, in relevant part, to ''any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).''). *See also* 84 FR at 27861–62 (discussing the Department's statutory interpretation).

[40] 45 CFR 92.2 (applying the final rule, in relevant part, to ''every *health* program or activity administered by the Department; and every *health* program or activity administered by a Title I entity'') (emphasis added).

Executive Agency.'' [41] They point out that HHS's Section 504 regulation applies to ''all programs or activities'' conducted by HHS and all its components, including CMS, HRSA, CDC, and SAMHSA.[42] Further, commenters stated that excluding non-Title I HHS-administered programs and activities, contrary to Section 504, will result in confusion and cause illogical results, whereby recipients would be covered by Section 1557 but the agencies administering the program would not be covered. For example, State Medicaid programs would be subject to Section 1557, but CMS, which oversees those Medicaid programs, would not be covered.

Response: Section 1557 is a nondiscrimination statute under the ACA, which uniquely applies to healthcare, whereas Section 504 is a statute of general applicability. Section 1557 incorporates Section 504's prohibited grounds of discrimination but not its scope: Section 1557's scope differs from that of the underlying statutes. For instance, Section 504 does not include ''contracts of insurance'' in its definition of Federal financial assistance,[43] but this final rule follows the text of Section 1557 by including ''contracts of insurance'' within Federal financial assistance.[44] With respect to CMS, it is covered under this final rule to the extent that it either administers health programs and activities receiving Federal financial assistance or administers programs and activities under Title I. In addition, it is important to note that, as a federal agency, CMS has long been subject to various constitutional and statutory prohibitions on discrimination.

c. § 92.3(b): Scope of the Term ''Health Program or Activity''

The Department proposed in § 92.3(b) to clarify that ''health program or activity'' encompasses all of the operations of entities ''principally engaged in the business of providing healthcare'' that receive Federal financial assistance. The Department proposed to further clarify that for any entity not principally engaged in the business of providing healthcare, such entity's operations are subject to the Section 1557 Rule only to the extent any such operation receives Federal financial assistance provided by the Department.

Comment: Commenters opposed limiting application of the rule when the entity is not principally engaged in the business of providing healthcare. Commenters argued that this would dramatically limit the scope of the rule and is contrary to Congressional intent and the plain meaning of the statute, which covers ''any health program or activity, any part of which is receiving Federal financial assistance. . . .'' Commenters stated that the entire entity receiving Federal financial assistance should be covered, not just the portion receiving funding. Commenters also argued the new framework would cause uncertainty and confusion for covered entities, which would have to clarify the extent of their own compliance, and also would make it harder for consumers to enforce their rights because they would have difficulty determining which entities and which portion of their programs or activities are subject to the rule. Commenters contended this uncertainty could result in lack of access to care, increased health disparities, and increased uncompensated care, all of which would increase overall healthcare costs.

Some commenters stated that the rule incorrectly incorporates the Civil Rights Restoration Act (CRRA) [45] into Section 1557. Commenters argued that the CRRA predates the ACA; nothing in the CRRA's text applies it to future statutes or Section 1557; Congress did not incorporate the CRRA into the Section 1557 statute; and Section 1557 itself is more expansive than the laws amended by the CRRA. Therefore, they say, a broader definition of covered programs and activities should apply to include all health insurers as covered entities. Others argued that the proposed rule's application of the CRRA contravenes the approach taken by Congress in the CRRA. They stated that Congress made clear in the CRRA that if any part of a program or activity receives Federal financial assistance, the entire program or activity must comply with the applicable civil rights laws. Thus, the commenters argued that the proposed rule's limited application when entities are not principally engaged in the business of healthcare, to cover only the specific operation that receives Federal financial assistance, is contrary to the CRRA. Another commenter stated that incorporating the CRRA into Section 1557 would be subject to judicial review, to the extent the Department relies on Section 1557's references to ''grounds'' and ''enforcement mechanisms'' of the underlying statutes to do so, because the Supreme Court held in *Consolidated Rail Corp.* v. *Darrone* that a statute's incorporation of another statute's enforcement mechanisms does not necessarily incorporate its substantive law.[46]

Conversely, other commenters were supportive of reducing regulatory burden by limiting application of the rule in this way. They stated that the 2016 Rule defined ''covered entities'' far too broadly, and that narrowing the scope will help rein in the regulatory excess of that rule. Commenters explained that healthcare entities often provide a variety of services and products, such as insurance coverage for life, disability, or short-term limited duration insurance coverage, and third-party administrative services, which do not receive Federal financial assistance. These commenters agreed that Section 1557 is intended to apply only to those programs receiving Federal funding and not to other parts of the entity's businesses or products when an entity is not principally engaged in the business of providing healthcare.

Response: Section 1557 explicitly incorporates statutes amended by the CRRA, and in this final rule the Department is aligning Section 1557's definition of ''health program or activity'' with the standard articulated in the CRRA in order to provide clarity and consistency. The CRRA clarified the scope of nondiscrimination prohibitions under the civil rights statutes that Section 1557 incorporates. For example, with respect to the health sector, it applied those prohibitions to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance: It applied ''program or activity'' to cover all of the operations of an entity only when that entity is ''principally engaged in the business of providing . . . health care . . . .'' [47] This final rule clarifies that the term ''health program or activity'' used in Section 1557 should be understood in light of the CRRA's limitations on the term ''program or activity'' as applied to statutes on which Section 1557 relies. As for *Consolidated Rail Corp.* v. *Darrone,* Congress specifically and intentionally

[41] 29 U.S.C. 794 (applying to ''any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service'').

[42] 45 CFR, part 85.

[43] 45 CFR 84.3(h).

[44] 42 U.S.C. 18116(a).

[45] Public Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

[46] *See Consolidated Rail Corp.* v. *Darrone,* 465 U.S. 624, 635 (1984) (holding that Section 504's incorporation of the ''remedies, procedures, and rights'' set forth in Title VI did not mean that Section 504 incorporated Title VI's substantive limitations on actionable discrimination).

[47] *See, e.g.,* CRRA § 3(a) (adding § 908(3)(A)(ii) to Title IX of the Education Amendments of 1972 (codified at 20 U.S.C. 1687(3)(A)(ii)).

overturned that case through the passage of the CRRA.[48]

The 2016 Rule also articulated a standard for ''health program or activity'' that relied upon the ''principally engaged'' prong of the CRRA, which was contested neither before nor after that rule's publication. In the regulatory text, the 2016 Rule defined ''health program or activity'' to apply to all operations of an entity only when it is principally engaged in providing or administering health services, health insurance coverage, or other health coverage.[49] The 2016 Rule preamble clarified that if an entity is not principally engaged in providing health benefits, the Department would apply the rule to its Federally funded health programs and activities.[50]

The Department believes that by specifying the degree to which the Section 1557 regulation covers entities not principally engaged in the business of providing healthcare, this final rule more clearly and consistently applies the CRRA's limitations on ''health program or activity'' across the regulation. The Department agrees with commenters who suggest that in doing so this final rule also advances its goal of reducing regulatory burdens under the ACA in furtherance of Executive Order 13765.

Comment: Commenters argued that limiting the application of the rule to only the portion of the health program or activity that receives Federal financial assistance for entities not principally engaged in the business of providing healthcare is not consistent with the Department's application of Title VI as set forth in HHS's 2003 LEP guidance. This guidance provided that Title VI applies to all parts of a covered entity receiving Federal financial assistance, not just the portion receiving Federal funds.[51]

Response: As a policy guidance document, the Department's LEP guidance cannot be used to create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.[52] Accordingly, the scope of application as set forth under the CRRA and this final rule would prevail over any conflicting text in the Department's LEP guidance.

d. § 92.3(c) Health Insurance and Healthcare

The Department proposed in § 92.3(c) to state that an entity principally or otherwise engaged in the business of providing health insurance would not be considered to be principally engaged in the business of providing healthcare, and on that sole basis, subject to the Section 1557 regulation. The proposed rule sought comment on whether it should define ''healthcare'' in the rule according to the statutes cited in the proposed rule.

Comment: Several commenters supported the distinction between entities principally engaged in the business of providing healthcare and those principally engaged in the business of providing health insurance. As one commenter stated, ''[p]aying for healthcare is not providing healthcare.'' Other commenters were opposed to this distinction. They argued that it is not consistent with Section 1557's statutory text or the proposed regulatory text at § 92.3(a)(1), both of which specifically include ''contracts of insurance'' as an example of Federal financial assistance. They also stated that this limited application is not consistent with Congressional intent to expand access to healthcare and create new nondiscrimination protections in health insurance.

Some commenters argued that health insurance is inextricably linked with the provision of healthcare. They pointed out that the statutory definition of ''healthcare'' relied upon in the proposed rule is unrelated to either the ACA, health insurance, or discrimination, and thus is not intended for or relevant to Section 1557 or health insurance.[53] Further, they argued that the definition of ''health insurance coverage'' referenced in the proposed rule, 42 U.S.C. 300gg–91, actually bolsters the argument that health insurance includes healthcare, as it defines ''health insurance coverage'' to include ''benefits consisting of *medical care* (provided directly, through *insurance* or reimbursement, or otherwise and including items and services paid for as medical care)'' (emphasis added). They also pointed out that definitions in 42 U.S.C. 300gg–91 are most relevant to Section 1557 because Title I of the ACA relied upon this section for definitions.

Response: The CRRA defined ''program or activity'' in the underlying statutes to apply to all of an entities' operations when it is principally engaged in the business of providing ''healthcare.'' On the other hand, the 2016 Rule expansively interpreted Section 1557's application to ''health programs or activities'' to include all operations of entities that ''provide health insurance coverage or other health coverage,'' whether or not they provided healthcare. Prior to the 2016 Rule, the Department had not interpreted the CRRA's term ''healthcare'' to cover the operations of health insurance issuers (as such).

Commenters are correct that Section 1557 includes ''contracts of insurance'' as a type of Federal financial assistance. The Department agrees that health programs or activities that receive contracts of insurance from the Federal government are covered entities under Section 1557. But this does not mean that health insurers, as such, are health programs or activities.

The Department pointed to 5 U.S.C. 5371, as well as to 45 CFR 160.103, in order to support its conclusion that the plain meaning of ''healthcare'' differs from insurance. And although 42 U.S.C. 300gg–91 explicitly encompasses payment, ''group health plans,'' and ''definitions relating to health insurance'' specifically, it should not be taken out of context: It defines ''medical care'' as ''amounts paid for'' certain medical services, which is an appropriate definition in the health insurance field but not in the healthcare field generally. (When a doctor provides ''medical care,'' she is not providing ''amounts paid for'' medical services—she is providing the services themselves.) Other portions of 42 U.S.C. 300gg–91 also support the distinction between healthcare and health insurance: It says that ''health insurance coverage means benefits consisting of medical care,'' where ''medical care'' is defined as ''amounts paid for . . . the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,'' or

[48] *See McMullen* v. *Wakulla Cty. Bd. of Cty. Commissioners,* 650 F. App'x 703, 705 (11th Cir. 2016), citing S. Rep. No. 100–64, at 2 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 3, 3–4.

[49] 81 FR at 31467. In the proposed rule, the Department disagreed with the 2016 Rule's usage of ''health services, health insurance coverage, or other health coverage'' as overbroad and inconsistent with the statutory text of the CRRA that uses the term ''healthcare.'' *See* 84 FR at 27862–63. However, the Department agrees with the 2016 Rule's limitation based on whether the entity is principally engaged.

[50] 81 FR at 31385–86, 31430–32.

[51] 68 FR 47311, 47313 (Aug. 8, 2003) (''Coverage extends to a recipient's entire program or activity, *i.e.,* to all parts of a recipient's operations. This is true even if only one part of the recipient receives the Federal assistance.'').

[52] *See* U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), *https://www.justice.gov/opa/press-release/file/1012271/download;* U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *https://www.justice.gov/file/1028756/download.*

[53] *See* 84 FR at 27862 (citing the definition of ''health care'' at 5 U.S.C. 5371). Commenters noted that this definition pertains to Federal personnel pay rates.

''amounts paid for transportation primarily for and essential to medical care'' in the primary sense just defined, or ''amounts paid for insurance covering medical care'' in either the primary sense just defined or the secondary sense of transportation for medical care.[54] It does not say that health insurance is healthcare, and it twice relies on the commonsense distinction between medical care proper and the health insurance that covers and pays for such care. It thus supports the Department's view that a health insurer is principally engaged in the business of providing coverage for benefits consisting in healthcare, which is not the same as the business of providing healthcare. This final rule brings the 1557 regulation's scope of coverage closer to the plain meaning of the 1557 statute, especially as read in light of the CRRA's definition of ''program or activity.''

Comment: Commenters were concerned that § 92.3(c) would result in exempting many of the plans, products, and operations of most health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, third-party administrator services, or short-term limited duration insurance plans. Commenters feared this would allow health insurance issuers to conduct their other activities in a discriminatory manner. Several commenters were particularly concerned about excluding short-term limited duration insurance plans because these plans have been known to engage in discriminatory practices based on disability, age, and sex.

Other commenters, in contrast, supported the proposed revisions. They stated the 2016 Rule was overly expansive, created an un-level playing field, and resulted in disincentives for issuers to participate in HHS-funded programs, such as offering QHPs or Medicare Advantage plans. This resulted in Section 1557's covering products that Congress explicitly excluded from the rest of the ACA, such as excepted benefits and short-term limited duration insurance plans. Commenters argued it was unlikely that Congress intended Section 1557 to regulate the same plans it had excluded from the ACA.

Response: The Department agrees with commenters who stated that the overly broad reach of the 2016 Rule subjected many insurance products that were not intended to be covered by the ACA to burdensome regulation, inconsistent with Congressional intent.

In the proposed rule, the Department stated that Section 1557 does not apply to short-term limited duration insurance as such, but only if it were offered by an entity for which all of the entity's activities are encompassed by Section 1557, or if such insurance received Federal financial assistance.[55] Under this final rule, where short-term limited duration insurance (1) is offered by an entity that is not principally engaged in the business of providing healthcare, and (2) does not receive Federal financial assistance, the protections of Section 1557 would not apply to it. The Department will robustly enforce the nondiscrimination requirements for QHPs under Title I of the ACA, for Exchange plans established by the ACA, and for any other insurance plans that Section 1557 covers. The reasons that this final rule does not cover FEHB plans are discussed in the response to the next comment.

Comment: The Department received comments related to the exclusion of employer plans and excepted benefits as a result of § 92.3(c). Several commenters objected to the exclusion of self-funded group health plans under the Employee Retirement Income Security Act of 1974 (ERISA) and the Federal Employees Health Benefits (FEHB) Program. Commenters argued that FEHB plans should be covered as a contract of insurance with the Federal government. Some suggested that employer group health plans, including self-funded plans, receive substantial Federal financial assistance in the form of favorable income tax treatment and thus should be covered.

Other commenters strongly supported excluding employer plans. Commenters noted that employers and group health plans are already subject to other Federal laws that prohibit discrimination, and that few employer-sponsored plans receive Federal financial assistance. They stated that the 2016 Rule's broad coverage exceeded statutory authority, encumbered the design and operation of employer group health plans, invited litigation regarding plan benefits, and increased the potential for costly new mandates, all of which were likely to increase healthcare costs for employers and employees alike without adding any additional protections against discrimination. Some commenters expressed support for the provision that third-party administrators of self-funded group health plans would no longer be subject to Section 1557 merely because other portions of their business receive Federal funding.

Some commenters requested further clarification by recommending that the regulatory text at proposed § 92.3(c) be revised to specify that other types of plans should not be considered entities principally engaged in the business of providing healthcare, including self-funded or fully insured group health plans under ERISA; self-funded or fully insured group health plans not covered under ERISA that are sponsored by either governmental employers (''government plans'') or certain religious employers (''church plans'' or ''denominational plans''); and benefit plans and programs excepted under the ACA.[56]

Response: The Department continues to take the position that FEHB plans are not covered under this rule. Even if FEHB plans were considered ''contracts of insurance,'' as suggested by some commenters, they still would not fall under the scope of this rule because the contract would be with the Office of Personnel Management (OPM), which operates the FEHB Program, not with the Department. As noted above, this final rule does not extend the Department's enforcement authority to a covered entity that is not principally engaged in the business of providing healthcare to the extent of its operations that do not receive financial assistance from the Department.

The Department agrees that this final rule will accomplish the Department's goal of reducing regulatory burden. The Department declines to offer further examples of non-covered entities in the regulatory text, as the rule's existing parameters are intended to broadly address different entities. To the extent that employer-sponsored group health plans do not receive Federal financial assistance and are not principally engaged in the business of providing healthcare (as set forth in the rule), they would not be covered entities. The same analysis would apply to employer-sponsored plans not covered by ERISA, such as self-insured church plans or

[54] 42 U.S.C. 300gg–91(b)(1), (a)(2).

[55] The Department notes by way of background that, subsequent to publication of the proposed rule, the U.S. District Court for the District of Columbia granted summary judgment for the Department, upholding its most recent rulemaking on short-term limited duration insurance. *See* Short-Term, Limited-Duration Insurance; Final Rule, 83 FR 38212 (August 3, 2018). The August 2018 final rule largely restored the long-standing definition for short-term limited duration insurance to the definition that was in effect from 1997 to 2016. The Court held that the restored definition was not arbitrary or capricious, finding that ''Congress clearly did *not* intend for the [ACA] to apply to all species of individual health insurance.'' *Association for Community Affiliated Plans* v. *U.S. Department of Treasury,* 392 F. Supp. 3d 22, 45 (D.D.C. 2019), *appeal filed* July 30, 2019.

[56] *See* 42 U.S.C. 300gg–91(c) (defining excepted benefits).

non-Federal governmental plans, as well as to excepted benefits.

Comment: Some commenters said that the proposed rule created confusion about whether QHPs are subject to the rule. Others requested clarification on the proposed rule's application to products offered through the Exchange. Others requested clarification on whether stand-alone dental plans and catastrophic plans, which are also sold through the Exchanges established under Title I, are covered under the rule. Another commenter requested confirmation that the proposed rule would not apply to individual or small-group market health insurance coverage that complies with the ACA but is sold outside of the Exchanges, regardless of whether the parent organization also offers on-Exchange QHPs. Others requested clarification as to how the rule would apply when one health insurance plan includes multiple types of enrollees, including subsidized Exchange enrollees, unsubsidized Exchange enrollees, and off-Exchange enrollees. The comments expressed concern that enrollees in the same plan deserved the same level of nondiscrimination protection and that the same standard should be applied.

Response: Health insurance products are often complex. While the Department provides general responses below in an attempt to clarify application of the rule, OCR will always engage in an individualized fact-based analysis when determining the extent of its jurisdiction over these or any other such products.

A QHP would be covered by the rule because it is a program or activity administered by an entity established under Title I (*i.e.,* an Exchange), pursuant to § 92.3(a)(3). A QHP could also be subject to Section 1557 if it were a recipient of Federal financial assistance, but as stated above, the premium tax credits that the Department plays a role in administering would no longer serve to bring an entity under the jurisdiction of this Section 1557 regulation.

Stand-alone dental plans and catastrophic plans offered through the Exchanges would similarly be subject to § 92.3(a)(3), as these plans are administered by an Exchange, which is an entity established under Title I.

Regarding ACA-compliant plans sold off-Exchange, because a health insurance issuer is not principally engaged in the business of providing healthcare, its operations would be subject to this rule only for the portion that receives Federal financial assistance. The issuer's components (*e.g.,* off-Exchange plans) that do not directly receive Federal financial assistance would not be subject to this rule.

Where a health insurance plan includes multiple types of enrollees, the Department would have to review the specific circumstance, but generally speaking, if a QHP is subject to Section 1557, this rule would apply consistently for all enrollees in the plan.

Comment: The Department received comments related to how the rule would apply to Medicare- and Medicaid-related products. One commenter asked whether the proposed limitation under § 92.3(c) would mean that Section 1557 would no longer apply to health insurance plans managed through Medicare and Medicaid.

A few commenters requested clarification on whether the proposed rule would apply to Employer Group Waiver Plans (EGWPs) and Medicare Part D Retiree Drug Subsidy (RDS) plans, or the employers that sponsor the plans. Commenters argued that applying the rule to these plans could disincentivize employers from sponsoring them and urged that the plans be exempt from the rule. Alternatively, one commenter requested that the Department exempt employer sponsors of ''800 series'' EGWPs, which are offered by Medicare Advantage Organizations (MAOs) or Part D Plan sponsors (PDP sponsors), because the employer is not the entity that receives funding from HHS. Finally, some commenters objected to excluding Medicare Part B from the rule.

Response: To be covered by the rule, a particular entity would have to satisfy one of the applicability requirements set forth in § 92.3. Entities that receive Federal funding through the Department's Medicare Part C (Medicare Advantage), Medicare Part D, or Medicaid programs would be subject to Section 1557 as recipients of Federal financial assistance. This would include Medicare Advantage plans, Medicaid managed care plans, EGWPs, or RDS plans, to the extent that they receive Federal financial assistance.

Pending further details, an employer that does not directly contract with CMS but offers an ''800 series'' EGWP through a MAO or PDP sponsor would not appear to be subject to this rule under this analysis because the employer does not receive the Federal financial assistance; meanwhile, the health insurance issuer offering the EGWP would be subject to the rule for its EGWP plan, due to receipt of either Medicare Part C or Part D funding.

As for Medicare Part B, it is not Federal financial assistance.[57] This remains unchanged from the 2016 Rule, which also determined that Medicare Part B was not Federal financial assistance under Section 1557.

Comment: Some commenters requested that this final rule be accompanied by explicit applicability guidance so that employers and plans could be able to ascertain if the final rule impacts their business.

Response: The Department seeks to provide sufficient clarity in this final rule. If OCR receives substantial questions about the rule's applicability after publication, OCR will consider issuing additional clarification, consistent with applicable law regarding issuance of sub-regulatory guidance.[58]

e. Summary of Regulatory Changes

For the reasons given in the proposed rule, and having considered comments received, the Department finalizes the proposed § 92.3, and repeal of § 92.2 of the 2016 Rule, without change, except that, as discussed in an earlier section of this preamble, and after considering comments on the issue, the Department is not finalizing the proposed repeal of § 92.2(c) concerning severability, but is retaining that provision and has moved it to § 92.3(d).

(4) Nondiscrimination Requirements in Proposed Revisions to § 92.2, and Repeal of § 92.8(d), 92.101, 92.206, 92.207, 92.209, and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d), 92.101, 92.206, 92.207, and Appendix B of the 2016 Rule (which includes repealing notice and taglines

[57] 45 CFR pt. 80 App A, No. 121; *https://www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-Federal-financial-assistance/301/index.html. See also* 81 FR at 31383, 31385; 84 FR at 27863 (discussing the applicability of the rule to Medicare Part B and clarifying in footnote 100 that ''[t]he 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).'').

[58] *See, e.g.,* Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, 84 FR 55239 (Oct. 9, 2019); Executive Order 13891 on Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 FR 55235 (Oct. 9, 2019); U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *https://www.justice.gov/file/1028756/download;* U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), *https://www.justice.gov/opa/press-release/file/1012271/download.*

provisions), and instead address nondiscrimination requirements in a new § 92.2. The Department proposed to repeal provisions that made applicable across all protected categories those particular requirements, prohibitions, or enforcement mechanisms that had previously applied only to particular circumstances.

The Department requested comments on all aspects of the proposed rule. The Department also specifically requested comment on any unaddressed discrimination on the basis of race, color, or national origin as applied to State and Federally-facilitated Exchanges, with any detailed supporting information. And the Department requested comment on whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and the rights of persons protected against discrimination on the basis of race, color, national origin, sex, disability, or age.

The Department received many comments on these proposed changes. The Department will first discuss comments concerning each of the grounds in Section 1557: Race, color, national origin, disability, age, and sex. Then other grounds of discrimination will be discussed, followed by assessment of claims of discriminatory conduct when multiple grounds of discrimination are alleged. Comments concerning disability and LEP protections will be addressed below in the section on Subpart B of the Section 1557 rule.

a. Discrimination on the Basis of Race, Color, or National Origin

i. Generally

Comment: The Department received support for its commitment to continued enforcement of race, color, and national origin protections. Commenters stated that these characteristics are clear and simple to distinguish, contrasting them with gender identity, which is fluid and more difficult to define.

Response: The Department appreciates the support for its continued commitment to the enforcement of protections against discrimination on the basis of race, color, and national origin. The Department agrees that gender identity as a category is difficult to define. This is not, however, the Department's reason for not viewing gender identity as a protected category under Section 1557. The Department enforces statutory prohibitions on discrimination on the basis of race, color, national origin, age, disability, and sex discrimination because they are set forth in the text of statutes incorporated into Section 1557, and gender identity is not set forth as a protected category in those statutes.

Comment: Commenters contended that the proposed changes, including repeal of § 92.101 and the specific discrimination it prohibited, will lead to confusion among individuals and lead healthcare providers to discriminate based on race, color, and national origin. Commenters recommended that the Department retain clear, strong language prohibiting healthcare providers from discriminating based on race, color and national origin.

Response: This final rule's § 92.2 retains clear, strong language prohibiting discrimination on the basis of race, color, or national origin. Covered entities are still required to provide the Department with an assurance, and, pursuant to the underlying civil rights regulations, to post notices, that they do not so discriminate and are in compliance with Federal civil rights law. If the Department learns of confusion among covered entities or individuals as to their civil rights, it will consider issuing further guidance as needed.

Comment: Some commenters contended that the proposed changes will negatively impact women of color, who (according to these commenters) disproportionately rely on the short-term health plans that this final rule does not cover, and are more likely to experience pregnancy-related issues that will cause them to suffer from the rollback of termination of pregnancy protections.

Response: For reasons detailed below, this final rule (a) does not generally apply to short-term limited duration health insurance and (b) only covers termination of pregnancy to the extent permitted by Title IX's abortion-neutrality language, as required by the relevant statutes. The Department will vigorously enforce the prohibitions on discrimination based on race or sex, including under disparate impact analysis with respect to race discrimination as provided for in the relevant Title VI regulations, but the Department remains bound by the limits of the statutes enacted by Congress. The Department's Office of Minority Health also supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: One commenter expressed concern that the changes in the proposed rule will have a negative impact on access to health screenings and vaccinations for patients. The commenter stated that removal of nondiscrimination requirements for many health insurance providers will leave these populations with little recourse if health insurance providers rescind coverage for preventative health services.

Response: Because this final rule continues to commit the Department to robust enforcement of its prohibitions on discrimination on the basis of race, color, national origin, sex, age, and disability, the Department does not anticipate that it will impede any population's access to preventive care and vaccinations, which (under separate provisions of the ACA) must be covered without cost sharing for group health plans and health insurance issuers offering group or individual health insurance coverage.[59]

ii. Repeal of Notice and Taglines Provisions at § 92.8(d) and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d) of the 2016 Rule, which required a nondiscrimination notice and taglines in all significant communications from covered entities, and also proposed to repeal the sample taglines notice in Appendix B to Part 92. 84 FR at 27857–60. The Department stated its assumption that this will correspondingly ease the burden of the LEP provision in CMS regulations at 45 CFR 155.205(c)(2)(iii)(A), which deemed compliance with the LEP provisions of the Section 1557 regulation to constitute compliance with CMS's requirements.[60]

The Department specifically sought comment to identify ''significant communications'' under the 2016 Rule sent by covered entities that include a notice and taglines but had not been considered by the analysis in the proposed rule, as well as the estimated annual volume of such communications. The Department also requested comment on which communications are significant in healthcare.

Comments: Some commenters stated that the removal of the 2016 Rule's notice and taglines provisions will result in LEP beneficiaries having less knowledge of available language assistance services and that they will likely rely more on family members to provide oral interpretation.

Response: The regulations of the underlying statutes referred to in Section 1557 (Title VI, Section 504, Title IX, and the Age Act) have long mandated that covered entities provide

[59] *See* 42 U.S.C. 300gg–13.

[60] 84 CFR 27887, n. 240, and 27881.

a notice of nondiscrimination.[61] This final rule maintains that requirement. Moreover, it continues to require covered entities to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity. It removes only the unduly broad, sometimes confusing, and inefficient requirement that all significant communications contain taglines. This requirement caused significant unanticipated expenses, as discussed in the regulatory impact analysis (RIA) below. Moreover, as discussed below, § 92.101 of this final rule reiterates longstanding criteria to help covered entities conduct an individualized assessment of their program and ensure meaningful access by persons with LEP, and retains the 2016 Rule's prohibition on covered entities' requiring an LEP individual to provide his or her own interpreter or relying on an accompanying adult to interpret or facilitate communication (except in limited circumstances).

Comment: Some commenters disagreed with the Department's proposal to make conforming amendments to the CMS requirements placed on Health Insurance Exchanges and Qualified Health Plan (QHP) issuers at 45 CFR 155.205. These commenters argued that the CMS requirements do not rely on the 2016 Rule's taglines provisions, nor does the 2016 Rule prevent the implementation of additional requirements in more specific programs, such as Medicaid and Medicare. Others agreed with the Department's proposal, raising concerns about CMS's requirements at 45 CFR 155.205, which state that Exchanges and QHP issues are only ''deemed'' in compliance with the CMS requirements ''if they are in compliance with'' the 2016 Rule's taglines provisions. These commenters argued that if the notice and taglines provisions are removed, the CMS compliance provision will cross-reference a repealed rule, which would require QHP issuers and Exchanges to comply with CMS's taglines rule instead. The CMS mandate for 15 taglines for the CMS list of critical documents is arguably as burdensome as the 2016 Rule's taglines provisions; therefore, these commenters argue that any benefit in efficiency yielded by the repeal of the 2016 Rule's taglines provisions would be lost for Exchanges and QHP issuers. These commenters suggest amending the 2016 Rule's provisions to state that there is no specific taglines requirement under Section 1557 and that a covered entity's compliance under applicable Federal and State laws will be considered under Section 1557's LEP meaningful access standards.

Response: The provision at 45 CFR 155.205(c)(2)(iii)(A) and the similar requirement placed on QHP issuers (see HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), have not been directly amended in this regard. Nevertheless, as the Department stated in the proposed rule,[62] both of those requirements depend on or refer to the taglines requirements repealed in this final rule. As a result, covered entities are deemed compliant with those particular taglines requirements due to this final rule. Specifically, 45 CFR 155.205(c)(2)(iii)(A) sets forth taglines requirements and then states, ''Exchanges, and QHP issuers that are also subject to § 92.8 of this subtitle, will be deemed in compliance with paragraph (c)(2)(iii)(A) of this section if they are in compliance with § 92.8 of this subtitle.'' The Department informed the public of this interpretation in the proposed rule, and after reviewing public comments, the Department maintains the same position for essentially the same reason. Because this final rule repeals the taglines requirements of the 2016 Rule at § 92.8, entities will not be out of compliance with those requirements, and therefore they will satisfy the condition of the sentence quoted above from 45 CFR 155.205(c)(2)(iii)(A) that they not be out of compliance with taglines requirements in 45 CFR part 92. Although the Department did not propose conforming amendments to those two regulations, and therefore cannot finalize such amendments in this final rule, the Department will consider making appropriate changes to other regulations in the future.

Comment: Commenters, including a health insurance issuer, noted that the 2016 Rule's preamble vaguely defined ''significant communications'' to 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. These commenters argued that because almost all written communications would be considered ''significant'' under this definition, most covered entities included a one- to two-page addition containing the nondiscrimination notice and taglines with most written communications. One health insurance issuer estimated sending the notice and taglines approximately 15 million times in 2018, or about five times for every individual served. One commenter stated that because the Department determined that the notice and taglines requirement in the 2016 Rule imposes a significant financial burden on covered entities, the Department is within its authority to rescind it, especially because of an executive order that limits the effectiveness of subregulatory guidance. Others requested that the Department issue further guidance on what constitutes ''significant'' documents and communications, instead of removing the 2016 Rule's notice and taglines provisions.

Response: The Department agrees with comments that stated the 2016 Rule's notice and taglines requirements were imprecise and overly burdensome. The Department declines to retain those requirements while merely issuing more guidance on what constitute significant communications. First, the requirements are not mandated by statute, and although the 2016 Rule is a regulation and not subregulatory guidance, the Department has determined that its financial burden on covered entities was not justified by the protections or benefits it provided to LEP individuals. Second, the Department believes that other protections as finalized in this rule (and discussed below) better serve the language access needs of LEP individuals and, therefore, are more appropriate. Repeal of the notice and taglines requirements in this rule does not repeal all other notice and taglines requirements that exist under other statutes and rules.

b. Discrimination on the Basis of Disability

The Department is committed under this final rule to enforce protections against discrimination on the basis of disability, both in specific provisions set forth in § 92.102–92.105, and as applicable through the underlying Section 504 regulations, which are more broadly applicable under Section 1557 of the ACA. Comments on these issues are discussed in the section below on Subpart B of the Section 1557 regulation.

c. Discrimination on the Basis of Age

Comment: Commenters expressed concerns that the changes in the proposed rule will lead to discriminatory practices in health plans. In the absence of explicit language prohibiting health plans from discriminating based on age as set forth in § 92.207 of the 2016 Rule, they alleged, health plans may unlawfully

[61] *See* Title VI (45 CFR 80.6 and Appendix to Part 80), Section 504 (45 CFR 84.8), Title IX (45 CFR 86.9), and the Age Act (45 CFR 91.32).

[62] 84 FR at 27881.

deny, cancel, or limit policies, deny or limit coverage for claims, impose additional cost-sharing on coverage, or use discriminatory marketing practices or benefit designs because of age. In particular, some commenters believe that health insurance plans will offer formularies and plan options that deny treatment for older individuals who generally have more health complications. For example, they say, this practice may already be in place with some health plans that offer coverage for hearing aids to children and youths but deny it to older adults. Some commenters said the proposed rule will lead to discrimination against older LGBT adults, who already have high levels of poverty and health disparities, and will contribute to worse health outcomes. Some commenters also alleged the proposed rule encourages unlawful discrimination against LGBT youth, who are already at increased risk of discrimination.

Response: This final rule retains clear language prohibiting discrimination on the basis of age, as defined in the Age Act and enforced through its implementing regulations, in any covered programs and activities, including health plan marketing and benefit design. Moreover, the ACA has specific provisions which limit the extent to which health plans offered under the ACA can charge higher premiums based on age, as well as specific provisions which require guaranteed issuance, address permissible cost sharing requirements, and establish standards for essential benefits and formularies.

The Department remains committed to vigorous enforcement of this prohibition on behalf of all Americans, including LGBT adults and youth. The Department declines to comment on specific cases outside of the normal enforcement process but encourages anyone who has experienced unlawful discrimination, including with respect to health plans, to file a complaint with OCR.

Comment: Commenters expressed concern that the proposed rule will lead to health plans using their benefit design to discriminate against individuals with chronic conditions who are more expensive to insure, including children and youth with serious health conditions. One commenter represented a 13 year old with Down syndrome who, the commenter said, was denied coverage by a private health insurer because that health insurer categorically denied coverage for individuals with Down syndrome.

Response: Many serious health conditions, including Down syndrome, qualify as disabilities under Section 504, which Section 1557 incorporates. The Department will enforce vigorously Section 1557's prohibition on discrimination on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design. As finalized, the amended § 147.104 would prohibit health insurance issuers from employing ''benefit designs that . . . 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.'' The ACA also establishes requirements, applicable to health insurance issuers offering individual and group health insurance, concerning guaranteed issuance and renewal.[63] Concerns about whether private health insurers are covered entities are addressed below in the section on this rule's scope of application.

Comment: Some commenters contended the proposed rule will allow health plans to place age restrictions on certain medications, such as age restrictions on contraceptives for youth.

Response: To the extent that covered entities (including health plans) place restrictions based on age, OCR would assess on a case-by-case basis whether such restrictions violate Section 1557's incorporation of grounds prohibited under the Age Act. The Age Act does not forbid certain age distinctions in Federal, State, or local statutes and ordinances, or an action that reasonably takes age into account as a factor that is necessary to the normal operation or achievement of a statutory objective of a program.[64]

d. Discrimination on the Basis of Sex

i. Generally

Comment: Commenters offered different points of view on the definition of the term ''sex,'' as this relates to the definition of discrimination ''on the basis of sex.''

A number of commenters stated that the Department had proposed a new definition of ''sex'' for the Section 1557 rule. Some objected that any reinterpretation of ''sex'' should be addressed by Congress or left to the courts, rather than administrative agencies. Others stated that the proposed regulations realign the Department's interpretation with several decades of Federal court decisions and with the logical interpretation based on the statute's plain meaning of sex (namely sex in its biological meaning), which until 2017 had been the consistent consensus of the Federal courts.

Some commenters said that sex is a binary reality of male and female, and that Title IX and Section 1557 apply this historic understanding of sex. Some commenters stated that there is no evidence in the legislative history of either Title IX or the ACA that Congress intended to prohibit gender identity or sexual orientation discrimination in Section 1557, and that the purpose of Title IX is to ensure women (as biologically distinct from men) equal opportunities in Federally funded programs and activities.[65] Commenters said that the 2016 Rule exceeded the Department's authority by adopting a new, different, or expansive definition of prohibited sex discrimination in its Section 1557 regulation, although Congress declined to do so when presented with the opportunity and instead incorporated its meaning from Title IX which was passed in 1972. Some commenters noted that Congress has repeatedly considered adding gender identity and sexual orientation as protected categories in nondiscrimination laws related to education,[66] or to employment,[67] or in bills that would redefine discrimination ''on the basis of sex'' [68] as the 2016 Rule attempted, but that Congress has chosen not to do so.[69] Where Congress has chosen to prohibit ''gender identity'' discrimination in other statutes, it added the term ''gender identity'' as a

[63] *See* 42 U.S.C. 300gg–1, 300gg.2.

[64] 45 CFR 90.14, 90.15.

[65] Commenters cited 118 Cong. Rec. 5808 (1972); 44 FR at 71423.

[66] See, *e.g., Student Non-Discrimination Act of 2018,* H.R. 5374, 115th Congress, 2nd sess.; online at: *https://www.congress.gov/115/bills/hr5374/BILLS-115hr5374ih.pdf*: ''No student shall, on the basis of actual or perceived sexual orientation or gender identity . . . be excluded from participation in, or be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.''

[67] *See, e.g., Employment Non-Discrimination Act of 2013,* S. 815, 113th Congress, 1st sess.; online at: *https://www.govtrack.us/congress/bills/113/s815/text*: ''It shall be an unlawful employment practice for an employer—(1) to fail or refuse to hire or to discharge any individual, or otherwise discriminate against any individual . . . because of such individual's actual or perceived sexual orientation or gender identity . . .''

[68] *See, e.g., Equality Act,* H.R. 5, 116th Congress, 1st sess.; online at: *https://www.congress.gov/116/bills/hr5/BILLS-116hr5rfs.pdf*; amends *Civil Rights Act of 1964* ''by striking 'sex,' each place it appears and inserting 'sex (including sexual orientation and gender identity)' . . .''

[69] *See* H.R. 1652, 113th Cong. (2013); S. 439, 114th Cong. (2015). H.R. 3185, 114th Cong. (2015); S. 1858, 114th Cong. (2015); H.R. 2015, 110th Cong. (2007); H.R. 2981, 111th Cong. (2009); S. 811, 112th Cong. (2011); *See* H.R. 4636, 103rd Cong. (1994).

new and separate category of prohibited grounds in addition to ''sex'' without redefining ''sex'' itself.[70] Other commenters said that reliance on legislative history is an improper method of statutory interpretation, and that the Supreme Court has deemed reliance on Congressional inaction to be inappropriate.

One commenter cited U.S. Supreme Court cases as setting forth the binding legal standard of sex discrimination as a binary biological concept. The commenter cited *Tuan Anh Nguyen* v. *I.N.S.* as rejecting an approach of ''[m]echanistic classification of all our differences as stereotypes'' because it obscures the reality that ''physical differences between men and women . . . are enduring,'' 533 U.S. 53, 73 (2001), as well as Justice Ginsburg's majority opinion in *United States* v. *Virginia,* which held that '' '[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.' '' 518 U.S. at 533 (1996).

Some commenters stated that changing cultural preferences should not be the standard for interpreting legal texts. Others analogized Title IX's lack of a definition of ''sex'' to the lack of a definition of ''race'' under the Civil Rights Act of 1964, where courts looked to the plain and ordinary meaning to interpret it as based on a person's ''family, tribe, people, or nation belonging to the same stock.'' Other commenters cited analyses of public meanings at the time of adoption, concluding that when ''gender'' was used, which was rare, it was used in contrast to sex: Gender referred to socially constructed roles, while sex, according to virtually every dictionary of the time, referred to biological differences between men and women.[71] Other commenters stated that use of the term ''gender'' (with regard to one's identity) as separate from ''sex'' (with regard to one's biology) is relatively new and is improperly interpreted today as evidence of support for gender-identity legal theories in prior legal precedents or decades-old statutes. Some commenters asserted that at the time of the passage of the underlying Federal civil rights statutes, ''sex'' and ''gender'' were commonly used identically under Title VII, Title IX, and the Equal Protection Clause to refer to biological sex.[72] However, other commenters disagreed, and stated that historical sources demonstrate the variability and complexity of the concept of sex to include ''[t]he sum of the morphological, physiological, and behavioral peculiarities of living beings.''

Some commenters stated that the terms male or female apply to everyone. Commenters stated that the ''sex'' of an organism is a clear, provable, objective, identifiable, biological, and binary reality according to relevant textbooks, studies, and articles from various specialties in the scientific community, including embryology, genomics, psychiatry, clinical anatomy, neuropsychology, developmental biology, genetics, endocrinology, neuropsychiatry, radiology, organismic and evolutionary biology, neuropharmacology, pediatrics, and pathology.[73] Healthcare providers stated that the reality of sex, as male or female, can be identified through advanced chromosomal testing such as karyotyping or simple genital identification at birth in roughly 99.98% of cases, leaving the remaining 0.02% as diagnoses with intersex or ambiguous conditions. Others stated that delineating a binary division on the basis of reproductive organs reflected an outdated paradigm and was not universally descriptive of transgender, transitioning, androgynous, intersex, two-spirit, or questioning individuals.

Some commenters stated that removal of a regulatory definition of ''sex'' leaves the regulation ambiguous, and the 2016 Rule was justified in clarifying by adding a definition that included gender identity and termination of pregnancy. Other commenters stated that the public widely understands the state of being either male or female, as determined by one's chromosomes or genetics, which leaves no ambiguity.

Response: Because Section 1557 incorporates Title IX's prohibition on discrimination ''on the basis of sex,'' it presupposes that the executive and judicial branches can recognize the meaning of the term ''sex.'' This final rule repeals the 2016 Rule's definition of ''on the basis of sex,'' but declines to replace it with a new regulatory definition. *See* 84 FR at 27857. Instead, the final rule reverts to, and relies upon, the plain meaning of the term in the statute.

''Sex'' according to its original and ordinary public meaning refers to the biological binary of male and female that human beings share with other mammals. As noted in briefs recently submitted by the Federal government to the Supreme Court, discrimination on the basis of sex means discrimination on the basis of the fact that an individual is biologically male or female.[74] Several commenters reference various sources of legislative history: That of Title IX, of Congress's decision to add protections on the basis of sexual orientation and gender identity to other statutes alongside protections on the basis of sex, and of Congress's repeated refusal to add those protections in other cases.[75] These sources support the plain

[70] 18 U.S.C. 249(a)(2).

[71] Commenters cited Joanne Meyerowitz, A History of ''Gender,'' 113 a.m. Hist. Rev. 1346, 1353 (2008); David Haig, The Inexorable Rise of Gender and the Decline of Sex: Social Change in Academic Titles, Archives of Sexual Behavior 1945–2001 (Apr. 2004); Sari L. Reisner, *et al.,* ''Counting'' Transgender and Gender-Nonconforming Adults in Health Research, *Transgender Studies* Quarterly 37 (Feb. 2015); New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010).

[72] *See Glenn* v. *Brumby,* 663 F.3d 1312, 1315 (11th Cir. 2011) (citing *City of Cleburne* v. *Cleburne Living Ctr., Inc.,* 473 U.S. 432, 440–41 (1985). (''In describing generally the contours of the Equal Protection Clause, the Supreme Court noted its application to this issue, referencing both gender and sex, using the terms *interchangeably* . . .'').

[73] Commenters cited texts including, *e.g.,* T.W. Sadler, Ph.D., *Langman's Medical Embryology* (Philadelphia: Lippincott Williams & Wilkins, 2004), 40; William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 519; Keith L. Moore, Ph.D., DSc, and T.V.N. Persaud, M.D., Ph.D. DSc, FRCPath., *The Developing Human: Clinically Oriented Embryology* (Philadelphia: Saunders/Elsevier, 2003), 35; Maureen L. Condic, Ph.D. and Samuel B. Condic, Ph.D., ''Defining Organisms by Organization,'' National Catholic Bioethics Quarterly 5, no. 2 (Summer 2005): 336; Lawrence S. Mayer, Ph.D., and Paul R. McHugh, M.D., ''Sexuality and Gender Findings from the Biological, Psychological, and Social Sciences,'' *New Atlantis* 50 (Fall 2016): 89; Scott F. Gilbert, Ph.D. *Developmental Biology* (Sunderland, Mass.: Sinauer Associates, 2016), 519–20; and William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 307; Nichole Rigby, M.A. and Rob J. Kulathinal, Ph.D., ''Genetic architecture of sexual dimorphism in humans,'' *J. of Cellular Physiology* 230, no. 10 (2015): 2305; Jonathan C.K. Wells, Ph.D., ''Sexual dimorphism of body composition,'' *Best Practice & Research: Clinical Endocrinology & Metabolism* 21 (2007): 415; Larry Cahill, Ph.D., ''His Brain, Her Brain,'' *Scientific American,* October 1, 2012; Larry Cahill, Ph.D. ''A Half-Truth Is a Whole Lie: On the Necessity of Investigating Sex Influences on the Brain,'' *Endocrinology* 153 (2012): 2542; Madhura Ingalhalikar, Ph.D., et al., ''Sex differences in the structural connectome of the human brain,'' *Proceedings of the National Academy of Sciences* 111 (January 2014): 823–28.

[74] *Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)); Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 4–5 (''When Congress enacted Title IX in 1972, the 'ordinary, contemporary, common meaning' of 'sex' was biological sex. . . . Title IX consistently uses 'sex' as a binary concept capturing only two categories: Male and female.'').

[75] Examples of bills where Congress chose not to enact prohibitions on discrimination on the basis of sexual orientation or gender identity include: The Employment Non-Discrimination Act (ENDA), which has been introduced ten times in the U.S. House of Representatives but has never proceeded out of committee: 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.

meaning of Title IX, but are not the only source of support for the Department's understanding of the meaning of the word ''sex.'' Contemporaneous dictionaries and common usage make clear that ''sex'' in Title IX means biological sex.[76] Even today, the article on gender dysphoria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition defines ''sex'' to ''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.'' [77] The term ''gender'' may sometimes be ambiguous. However, neither Title IX nor Section 1557 uses that term, and the ordinary public meaning of the term ''sex'' in Title IX is unambiguous. In order to avoid ambiguities associated with the term ''gender,'' the Department's regulations and guidance have, where relevant, distinguished sex (in its biological meaning) from gender, gender identity, or gender expression.[78]

Some commenters challenge the Department's approach by pointing to medical conditions that they refer to as ''intersex.'' The term refers to rare medical conditions that the medical literature, since 2006, has preferred to call ''disorders of sexual development'' (DSD).[79] DSD are estimated to be present in 0.0167%–0.022% of the population. More importantly, DSD are ''congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical.'' [80] This medical definition refers to, and presupposes, the ordinary biological and binary meaning of ''sex,'' just as the definition of any medical disorder presupposes an understanding of healthy baseline functionality.

Title IX,[81] along with its implementing regulations,[82] consistently understands ''sex'' to refer to the biological binary categories of male and female only.[83] The Department of Justice has recently noted that ''[i]f the term 'sex' in Title IX included 'gender identity'—which, according to the American Psychiatric Association, may include 'an individual's identification as . . . some category *other than* male or female,' *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition* 451 (2013) (emphasis added)—then multiple Title IX provisions would make little sense.'' [84] Many comments on the 2019 NPRM assume that Section 1557's protection against discrimination ''on the basis of sex'' covers women's health issues including pregnancy, uterine cancer, and prenatal and postpartum

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). Similarly, the Equality Act has been introduced in three successive sessions of Congress; it did not proceed out of committee in the 114th and 115th Congresses, and it passed the House of Representatives on May 17, 2019. *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).

[76] *See* New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010). Some Federal courts have gone farther, using the legislative history to show that ''Congress never considered nor intended'' for sex under Title VII (which is often used to interpret Title IX) to apply to ''anything other than the traditional concept of sex,'' and that coverage for a concept such as transgender status ''surely'' would have been mentioned in the legislative history had Congress intended such an ''all-encompassing interpretation.'' The Department finds the analysis in these Court decisions persuasive, but declines to rely on their reasoning. *See Ulane* v. *Eastern Airlines Inc.,* 742 F. 2d 1081, 1085 (7th Cir. 1984) (analyzing ''The total lack of legislative history supporting the sex amendment coupled with the circumstances of the amendment's adoption''); *see also Voyles* v. *Ralph K. Davies Medical Center,* 403 F. Supp. 456, 457 (N.D. Cal. 1975), *aff'd,* 570 F.2d 354 (9th Cir. 1978) (finding a ''void'' in the legislative history and concluding that Congress's ''paramount, if not sole, purpose in banning employment practices predicated upon an individual's sex was to prohibit conduct which, had the victim been a member of the opposite sex, would not have otherwise occurred. Situations involving transsexuals, homosexuals or bi-sexuals were simply not considered.'').

[77] American Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders,* 5th ed. (Arlington, VA: American Psychiatric Ass'n, 2013), 451–59.

[78] *See* 45 CFR 411.5; *also* 79 FR 77771, 84 FR 27854. *See* NIH, Office of Research on Women's Health, ''Sex & Gender,'' *https://orwh.od.nih.gov/sex-gender* (''NIH is committed to improving health by supporting the rigorous science that drives medical advances. Sex/gender influence health and disease, and considering these factors in research informs the development of prevention strategies and treatment interventions for both men and women. 'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time. . . . With continuous interaction between sex and gender, health is determined by both biology and the expression of gender.'').

For these reasons, in general throughout this document the Department prefers to use simply the term ''sex'' because the plain, ordinary meaning of ''sex'' is already biological, so it is generally redundant to use the term ''biological sex.'' Where the Department uses the term ''biological sex,'' or similarly ''biological male'' or ''biological female,'' it does so merely to emphasize this point and for the purposes of clarity in particular contexts, and not to imply that there is a distinction between biological sex and sex under the plain meaning of the term.

[79] R.L.P. Romao, J.L. Pippi Salle, and D.K. Wherett, ''Update on the Management of Disorders of Sex Development,'' *Pediatric Clinics of North America* 59 (2012), 853–69; I.A. Hughes, ''Disorders of Sex Development: A New Definition and Classification,'' *Best Practice & Research Clinical Endocrinology & Metabolism* 22:1 (2008), 119–34.

[80] A. Rawal and P. Austin, ''Concepts and Updates in the Evaluation and Diagnosis of Common Disorders of Sexual Development,'' *Current Urology Reports* 16:83 (2015), 1–9; I. Hughes et al., ''Consequences of the ESPE/LWPES guidelines for diagnosis and treatment of disorders of sex development,'' *Best Practice & Research Clinical Endocrinology & Metabolism* 21:3 (2007), 351–65; P.A. Lee et al., ''Consensus Statement on Management of Intersex Disorders,'' *Pediatrics* 118:2 (2006), e488–500.

[81] *See* 42 U.S.C. 1681(a)(2)(''both sexes''), (a)(2) (''one sex'' and ''other sex''), (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'').

[82] *See* language such as ''male and female,'' ''both sexes,'' ''each sex,'' ''one sex . . . the other sex,'' and ''boys'' and ''girls,'' at 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. *See* similarly 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.*

[83] Federal courts have also made this observation. *See, e.g., Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518, 522 (3d Cir. 2018) (''Sex' is defined as 'the anatomical and physiological processes that lead to or denote male or female.' Typically, sex is determined at birth based on the appearance of external genitalia.''); *Hively* v. *Ivy Tech Cmty. Coll.,* 853 F.3d 339, 362 (7th Cir. 2017) (''[i]n common, ordinary usage in 1964—and now, for that matter—the word 'sex' means biologically *male* or *female.*'') (Sykes, J., dissenting) (emphasis in original); *cf. id.* at 357 (''we, who are judges rather than members of Congress, are imposing on a half-century-old statute a meaning of 'sex discrimination' [to include sexual orientation] that the Congress that enacted it would not have accepted.'') (Posner, J., concurring); *G.G. ex rel Grimm* v. *Gloucester Cnty. Sch. Bd.,* 822 F.3d 709, 736 (4th Cir. 2016) (''Title IX was enacted in 1972 and the regulations were promulgated in 1975 and readopted in 1980, and during that time period, virtually every dictionary definition of 'sex' referred to the physiological distinctions between males and females, particularly with respect to their reproductive functions.'') (Niemeyer, J., dissenting); Statement of Interest for DOJ, *Soule* v. *Connecticut Association of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5 (''Other provisions of Title IX employ ''sex'' as a binary term, and thus provide further confirmation that the prohibition on ''sex'' discrimination does not extend to discrimination on the basis of transgender status or gender identity.''); *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 687 (N.D. Tex. 2016) (''the meaning of sex unambiguously refers to the biological and anatomical differences between male and female students as determined at their birth,'' quoting *Texas* v. *United States,* 201 F. Supp. 3d 810, 833 (N.D. Tex. 2016)); *Johnston* v. *Univ. of Pittsburgh of Commw. Sys. of Higher Educ,* 97 F. Supp. 3d 657, 676 (W.D. Pa. 2015) (''[o]n a plain reading of the statute, the term 'on the basis of sex' in Title IX means nothing more than male and female, under the traditional binary conception of sex consistent with one's birth or biological sex'').

[84] Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

services. That assumption is correct: These issues are protected under Section 1557 because of the ordinary and biological meaning of ''sex.''

Prior to the ACA, OCR itself had always applied Title IX in its enforcement actions using the biological binary meaning of sex.[85] Recently, OCR has resolved a number of Section 1557/Title IX cases of discrimination against women in healthcare programs and activities funded by the Department, again relying on a biological understanding of sex.[86] The 2016 Rule itself presupposed the biological meaning of sex when it permitted ''sex-specific'' health programs that are ''restricted to members of one sex,'' when it incorporated ''termination of pregnancy'' into discrimination on the basis of sex, and when it referred repeatedly to ''sex assigned at birth.'' [87]

Supreme Court case law on Title IX has consistently presupposed the biological and binary meaning of ''sex.'' [88] Even when some lower courts have recently extended Title VII or Title IX protections ''on the basis of sex'' to encompass gender identity, they have done so only by presupposing the ordinary public meaning of ''sex'' as a biological binary reality. In *Whitaker* v. *Kenosha Unified Sch. Dist.,* for example, the Seventh Circuit stated: ''Here, the School District's policy cannot be stated without referencing sex, as the School District decides which bathroom a student may use based upon the sex listed on the student's birth certificate. This policy is inherently based upon a sex-classification and heightened review applies.'' [89] Likewise, in *Harris Funeral Homes,* the Sixth Circuit stated: ''Here, we ask whether Stephens would have been fired if Stephens had been a woman who sought to comply with the women's dress code. The answer quite obviously is no. This, in and of itself, confirms that Stephens's sex impermissibly affected Rost's decision to fire Stephens.'' [90] In other words, Stephens ''quite obviously'' is not ''a woman'' because ''Stephens's sex'' is male.[91]

The Department does not deny that some courts have caused confusion as to the meaning of sex in civil rights law. Conflicting views in the lower courts, however, do not preclude the Department, consistent with the position of the U.S. government, as set forth in briefs filed in the Supreme Court, from returning to its decades-long practice of conforming to the original and ordinary public meaning of ''sex'' in Title IX, a meaning that continues to be presupposed even in the same rulings that have caused this confusion.

Some lower courts have recently held that discrimination ''on the basis of sex'' encompasses gender identity or sexual orientation even when ''sex'' is understood in its ordinary, biological, and binary sense. These views will be addressed below in the relevant subsections.

Comment: Some commenters argued that the proposed rule would be inconsistent with the purposes of the ACA; that the weight of law recognizes sexual orientation and gender identity as forms of sex discrimination; and that the proposed rule would undermine Congress's intent to expand access to healthcare and healthcare coverage. Commenters emphasized that it is unacceptable for a healthcare facility to deny medical care to a patient based on the patient's sexual orientation or transgender status.

Response: The Department does not condone the unjustified denial of needed medical care to anyone, and believes that everyone, regardless of gender identity or sexual orientation, should be treated with dignity and respect. The Department must interpret Congress's purpose in passing the ACA by reading that statute's plain text. The ACA sought to expand access to healthcare and healthcare coverage through some means but not others: in particular, Congress saw fit to incorporate into the ACA certain nondiscrimination protections, and not others. For example, in the unlikely event that a healthcare provider were to deny services to someone based solely on his or her political affiliation, the Department would not be able to address such denial of care under Section 1557. Under this final rule, OCR is committed to no less than full enforcement of the prohibitions on discrimination that Congress included in Section 1557, without exceeding the statutory text. Unlike other bases of discrimination, the categories of gender identity and sexual orientation (as well as political affiliation) are not set forth in those statutes.[92]

Comment: Some insurers stated that they already took steps to come into compliance with prohibitions related to gender identity and termination of pregnancy in their plans under the 2016 Rule, and that they will incur burdens to change their plans. Other commenters stated that the 2016 Rule created burdens that, if unrelieved, would encumber their day-to-day affairs and limit their ability to provide healthcare services for their patients or healthcare coverage for their employees.

Response: As discussed in the Regulatory Impact Analysis below, this rule removes certain requirements, without requiring providers to incur new burdens related to those requirements. Whether or not the Department revises the regulation, the past expenditures incurred by insurers and other commenters to come into

[85] In the 2015 NPRM, the earliest record of the Department's new understanding of sex discrimination cited was an OCR letter dated 12 July 2012. 80 FR 54176.

[86] U.S. Department of Health and Human Services, ''HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination'' (2018), *https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html*; ''OCR works with DOJ to ensure Federally funded medical center provides communication services for deaf and hard of hearing patients'' (2018), *https://www.hhs.gov/about/news/2017/12/20/ocr-works-with-doj-to-ensure-Federally-funded-medical-center-provides-communication-services-for-deaf-and-hard-of-hearing-patients.html*; ''HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar'' (2019), *https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html* (requiring chaperone policies where patients can request a chaperone of the same sex, meaning biological sex, during sensitive physical examinations).

[87] *See* 81 FR 31384, 31387, 31406, 31408–09, 31428, 31429, 31435, 31436, 31467, 31470, 31471, 31472.

[88] *See, e.g., Nat'l Collegiate Athletic Ass'n* v. *Smith,* 525 U.S. 459, 464 (1999) (Title IX claim based on allegation ''that the NCAA discriminates on the basis of sex by granting more waivers from eligibility restrictions to male than female postgraduate student-athletes''); *Cannon* v. *Univ. of Chicago,* 441 U.S. 677, 680 (1979) (Title IX claim based on allegation that plaintiff's ''applications for admission to medical school were denied . . . because she is a woman'').

[89] 858 F.3d 1034, 1051 (7th Cir. 2017).

[90] *Equal Emp't Opportunity Comm'n* v. *R.G. & G.R. Harris Funeral Homes,* 884 F.3d 560 (6th Cir. 2018), 575. *See also* certain passages during oral argument on appeal at the U.S. Supreme Court, *e.g.:* ''here, Ms. Stephens, was being treated differently because of her sex. . . .Yes, if she had not been a—if she had not been assigned at birth the sex that she was assigned at birth, she would have been treated differently'' (Kagan, J., Transcript of Oral Argument at 41, *R.G. & G.R. Harris Funeral Homes, Inc.* v. *E.E.O.C.,* 139 S. Ct. 1599 (2019) (No. 18–107), *https://www.supremecourt.gov/oral_arguments/argument_transcripts/2019/18-107_4gcj.pdf*); *See also* Mr. Cole, counsel for respondents at oral argument, *Id.* at 4–5: ''None of [our] arguments ask this Court to redefine or, in Judge Posner's words, update sex. They assume, arguendo, that sex means at a minimum sex assigned at birth based on visible anatomy or biological sex.'' *Id.* at 28: ''[O]ur argument rests on text meaning, at a minimum, sex assigned at birth or biological sex, and everybody agrees— . . . [we are] asking you to interpret the statute as it is written and as everybody agrees it applies to sex assigned at birth.''

[91] *Harris* 884 F.3d at 575. It is true that the *Harris* court referred to Stephens with female pronouns throughout the rest of its ruling, but it appeared to do so based on its concept of gender identity, not of sex. Had the *Harris* court employed female pronouns in the quoted passage, it would have visibly undermined the basis of its Title IX analysis.

[92] The Department responds below to comments with respect to sexual orientation and gender identity specifically.

compliance with the 2016 Rule are ''sunk costs'' that cannot be recovered. With the finalization of this rule, insurers have the option—as they have had since December 31, 2016—of providing such coverage or not. Presumably some insurers will maintain coverage consistent with the 2016 Rule's requirements and some will not. The final rule also does not alter the status quo, and thus does not impose burdens in this regard, because, independent of the finalization of this rule, the 2016 Rule's provisions on gender identity and termination of pregnancy have been vacated by a final order and decision of a federal court.

Comment: Commenters expressed concern that the proposed rule would result in lack of information about gender transition-related services or termination of pregnancy, leaving patients without information about different surgical procedures and prescription options, and in danger of harm. Some argued that women, members of the LGBT community, people with disabilities, people with LEP, and racial minorities need additional specific protections because they will face greater burdens accessing healthcare due to ''intersectionality'' theories. Others, however, said it was not appropriate or reflective of current civil rights law to analogize sexual orientation or gender identity to race or other protected categories.

Some commenters argued that the 2016 Rule had decreased LGBT patients' fears of discrimination, that the proposed rule will lead to discrimination against them (including by States, providers, marketplaces, agents, and brokers), and that this will increase their health disparities, mainly via poorer quality of care, lack of access to willing providers especially in rural areas, postponed care including preventive care, increased healthcare and insurance costs, and impediments to HIV patients' access to medication. Commenters said the rule would undermine the President's goal of eradicating HIV. Commenters relied on national and statewide reports and studies highlighting harm faced by LGBT people due to inadequate healthcare, including an increase in substance abuse; worsening psychiatric disorders; untreated depression leading to suicide; and higher rates of AIDS, HIV and other STIs, cancer, and behavioral health issues. These commenters also argued the proposed rule would permit LGBT people to suffer discrimination and hence stigmatic injury, which could also deter them from disclosing their LGBT status to their physicians and seeking proper care. Commenters alleged high rates of mental conditions (*e.g.,* depression),[93] behavioral conditions (*e.g.,* substance use disorder),[94] developmental conditions (*e.g.,* autism, learning disabilities), and physical conditions (*e.g.,* HIV, heart disease) among the LGBT population. Commenters also expressed concerns about lack of communication and consent between providers and patients, and alleged that the risk of discrimination is heightened in vulnerable populations, including persons with developmental disabilities, persons with LEP, elderly patients with diminished capacity, and those who rely on surrogates or guardians for making medical decisions on their behalf. Others stated that OCR does not have authority to protect all forms of discrimination that may negatively impact people, but that it must act within its statutory authority.

Response: The Department is concerned with the health of all Americans. It acts to the fullest extent of its statutory authority in its efforts to improve the health and wellbeing of all. Under its civil rights authority, it enforces Federal laws requiring nondiscrimination on specified grounds, which in the case of Section 1557 are race, color, national origin, sex, age, and disability. When OCR receives a claim alleging multiple grounds of prohibited discrimination, the Department analyzes the elements of each claim according to the statute applicable to that ground.

Consistent with the text of the ACA and, in this case, the underlying civil rights statutes incorporated into the ACA, the Department seeks, wherever possible, to remove barriers to healthcare. Those barriers include regulations that impede providers' ability to offer healthcare by interfering with their conscientious medical judgments or imposing unnecessary cost burdens on them. By removing such provisions from the 2016 Rule, the Department hopes to increase the availability of healthcare to all populations.

As a matter of policy, the Department recognizes and works to address barriers to treatment caused by stigma about depression, anxiety, substance use disorder, and other comorbid mental and behavioral health conditions.[95] With regard to HIV, this final rule does not alter or affect the longstanding Federal protections against discrimination for individuals with HIV: Section 504, and hence also this final rule, prohibits discrimination on the basis that an individual has HIV.[96] OCR continues to pursue major enforcement actions under its authorities [97] and to provide the public guidance [98] to protect the rights of persons with HIV or AIDS. HHS remains committed to ensuring that those living with HIV or AIDS receive full protection under the law, in accordance with full implementation of the President's National HIV/AIDS Strategy.[99]

Regarding commenters' worries about informed consent, this final rule does not repeal any informed consent requirements. Besides many relevant State laws,[100] CMS regulations also

[93] Commenters cited Remafedi G, French S, Story M, et al., The Relationship Between Suicide Risk and Sexual Orientation: Results of a Population-Based Study. Am J Public Health. 1998;88(1):57–60; McLaughlin KA, Hatzenbuehler ML, Keyes KM. Responses to Discrimination and Psychiatric Disorders Among Black, Hispanic, Female, and Lesbian, Gay, and Bisexual Individuals. Am J Public Health. 2010;100(8):1477–84.

[94] Commenters cited Banez GE, Purcell DW, Stall R, et al., Sexual Risk, Substance Use, and Psychological Distress in HIV Positive Gay and Bisexual Men Who Also Inject Drugs. AIDS. 2005;19 (suppl. 1):49–55.

[95] *See, e.g.,* Pain Management Task Force, ''Pain Management Best Practices, Fact Sheet on Stigma'' (Aug. 13, 2019), *https://www.hhs.gov/sites/default/files/pmtf-fact-sheet-stigma_508-2019-08-13.pdf* (''Compassionate, empathetic care centered on a patient-clinician relationship is necessary to counter the suffering of patients . . . . Patients with painful conditions and comorbidities, such as anxiety, depression or substance use disorder (SUD) face additional barriers to treatment because of stigma.'').

[96] *See* 29 U.S.C. 705(20) (incorporating ADA definition of disability into Section 504); 42 U.S.C. 12102(1)–(3); 28 CFR 35.108(d)(2)(iii)(J).

[97] *See, e.g.,* ''HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination'' (Oct. 30, 2019), *https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html*; ''HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination'' (Sept. 8, 2017), *https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html.*

[98] *See* OCR, ''Know the Rights That Protect Individuals with HIV and AIDS,'' *https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/hivaids.pdf*; OCR, ''Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS,'' *https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html.*

[99] *See* ''Ending the HIV Epidemic: A Plan for America,'' *https://www.hiv.gov/Federal-response/ending-the-hiv-epidemic/overview.*

[100] *See, e.g.,* Alaska Stat. § 09.55.556(a); Ark. Code Ann. § 16–114–206; Del. Code Ann. tit. 18, § 6852; Ga. Code Ann. § 31–9–6.1; Haw. Rev. Stat. § 671–3; Idaho Code Ann. § 39–4304; Ind. Code § 16–36–1.5–7; Ky. Rev. Stat. Ann. § 304.40–320; La. Rev. Stat. Ann. § 40:1299.40; Me. Rev. Stat. Ann. tit. 24 § 2905; Neb. Rev. Stat. § 44–2816; Nev. Rev. Stat. § 449.710; N.Y. Pub. Health Law § 2805–d; N.C. Gen. Stat. § 90–21.13; Or. Rev. Stat. § 677.097; 40 Pa. Cons. Stat. § 1303.504; Tenn. Code Ann. § 29–26–118; Tex. Rev. Civ. Stat. Ann. art. 4590i, § 6.02;

Continued

require, as a condition of participation in Medicare, that patients (or their legal surrogate) have the right to make informed decisions, the right to surgical informed consent policies,[101] and the right to properly executed informed consent forms.[102] Most States' malpractice laws address negligent failure to communicate risks and benefits of medical treatment options. Basic elements of informed consent with respect to participation in a clinical trial, for example, include: (1) Providing information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate.[103]

The Department knows of no data showing that the proper enforcement of Federal nondiscrimination law according to statutory text will disproportionately burden individuals on the basis of sexual orientation and/or gender identity. Because the 2016 Rule explicitly declined to make sexual orientation a protected category, and because the Rule's gender identity provision has been legally inoperative since December 31, 2016, to the extent that LGBT individuals suffer future harms, it cannot be attributed to the Department's finalizing this rule, as opposed to other causes.

Comment: Commenters raised concerns that, without the 2016 Rule's provisions, certain insurers, such as those offering short-term limited duration insurance plans, would not offer coverage for conditions that affect only women, such as uterine cancer. Some commenters stated that the underlying Title IX regulatory provisions are insufficient by themselves to address access to insurance coverage of procedures provided to a single sex in healthcare. Some commenters stated that, without the 2016 Rule, women would not be able to afford insurance for medical and hospital care.

Response: The Department is strongly committed to promoting women's health. The Department enforces or implements ACA provisions that protect patient access to obstetrical and gynecological care.[104] The Department also enforces other provisions, both within and outside the ACA, that, for example, provide for maternity and newborn care as essential health benefits,[105] require coverage of women's preventive health services,[106] establish (as a matter of statute) the HHS Office of Women's Health and the Pregnancy Assistance Fund,[107] and promote young women's breast health awareness.[108]

The Department's commitment to women's health also includes vigorous enforcement of Section 1557's prohibition on sex-based discrimination. Under HHS's Title IX regulations, which OCR will use for enforcing Section 1557, covered entities must provide medical insurance benefits, services, policies, and plans without discrimination on the basis of sex. This does not preclude a covered entity's providing a covered benefit or service that is used uniquely by individuals of one sex or the other, such as uterine cancer treatments. However, any plan that includes full-coverage health insurance or services must encompass gynecological care.[109] As discussed in the relevant section below, the Department is bound by applicable law in determining the extent to which Section 1557 covers short-term limited duration insurance.

Comment: Some commenters said that the Department was wrong to claim in the 2019 NPRM that State and local entities are better equipped to address issues of gender dysphoria or sexual orientation, because they say that fifty percent of the LGBT population lives in States without laws prohibiting insurance companies from discriminating based on LGBT status. Others said that, because States like New York explicitly protect persons who identify as LGBT, the new rule will cause confusion for providers and patients about people's rights under Federal and State law. Some commenters suggested that including gender identity and sexual orientation in the Final Rule would reduce ambiguity in its interpretation and implementation.

Response: States and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law, including healthcare civil rights law. That is precisely why, under our Constitutional Federal system, it is appropriate not to preempt States' diverse views on these topics without a clear mandate from Congress to do so. This final rule complies with the federalism-related portions of Executive Orders 12866 and 13132 by avoiding undue interference with State, local, or tribal governments in the exercise of their governmental functions. It leaves them free to balance the multiple competing considerations involved in the contentious and fraught set of questions surrounding gender dysphoria and gender identity, and to adopt protections on the basis of sexual orientation or gender identity to the extent that they see fit (so long as they comply with Federal law).[110]

The Department notes, furthermore, that under the guaranteed issuance and renewal provisions of the ACA, health insurance issuers that offer health insurance coverage in the individual or group market in a state must accept every employer and every individual in that state that applies for such coverage, and must renew or continue in force such coverage at the option of the plan sponsor or the individual. *See* 42 U.S.C. 300gg–1 (guaranteed issuance), 300gg–2 (guaranteed renewability). Federal law similarly limits the bases on which a health insurance issuer can vary premium rates in the individual or small group market; such bases are limited to type of coverage (individual or family), rating area, age, and tobacco use. 42 U.S.C. 300gg. Thus, commenters' concern that LGBT individuals could be denied coverage if the Section 1557 rule does not include gender identity (or sexual orientation) is misplaced.

Comment: One commenter expressed concern that the proposed rule will have an effect beyond the United States by showing the international community that the United States Federal government does not recognize protections for individuals based on gender identity or sexual orientation in healthcare.

Response: The Department is not primarily responsible for the United States' foreign relations. Moreover, the Department has an obligation to implement the statutes according to the plain language of the text passed by Congress (unless unconstitutional), regardless of international implications.

Comment: Some commenters requested that the Department retain all guidance it had issued under the 2016 Rule. Other commenters stated that components of HHS continue to offer

Utah Code Ann. § 78–14–5; Vt. Stat. Ann. tit. 12, § 1909; Wash. Rev. Code Ann. § 7.70.050; Wis. Stat. Ann. § 448.30.

[101] 42 CFR 482.51(b)(2).

[102] 42 CFR 482.24(c)(4)(B)(v).

[103] 45 CFR 46.116–117 (HHS Office of Human Research Subject regulations).

[104] *See, e.g.,* 42 U.S.C. 300gg–19a(d).

[105] 42 U.S.C. 18022(b)(1)(D).

[106] 42 U.S.C. 300gg–13.

[107] 42 U.S.C. 237a; 42 U.S.C. 18202.

[108] 42 U.S.C. 280m.

[109] *See, e.g.,* 45 CFR 86.39.

[110] Ambiguity in the 2016 Rule's provisions regarding gender identity is addressed below. The Department further notes that sexual orientation was explicitly rejected as a protected category under the 2016 Rule. 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.'').

inconsistent guidance about the legal interpretation of the 2016 Rule.

Response: The Department stated in the preamble to the proposed rule that guidance under the 2016 Rule that conflicted with the proposed rule was suspended until further notice.[111] All such guidance is hereby withdrawn, effective upon publication of this final rule, and is in the process of being removed from the Department's website. Pursuant to Executive Order 13891, the Administration is also undertaking efforts to comprehensively review guidance documents ''to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations,'' [112] which also requires removal of inconsistent guidance from departmental websites.

ii. Gender Identity, Including Single-Sex Services Under § 92.206 of the 2016 Rule

The Department proposed to repeal the 2016 Rule's definition of ''on the basis of sex'' to encompass gender identity, which the 2016 Rule defined 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.'' [113] The Department also proposed to repeal § 92.206 of the 2016 Rule, which has three elements. First, the section required covered entities not to discriminate ''on the basis of sex'' (as defined in § 92.4 of the 2016 Rule) in providing access to health programs and activities. Second, it required them to ''treat individuals consistent with their gender identity.'' Third, it prohibited covered entities from ''deny[ing] or limit[ing] 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.'' [114]

Comment: Commenters offered varying views on the state of gender-identity nondiscrimination protections under current Federal law. Some commenters alleged that it is settled law that Section 1557 prohibits gender identity discrimination. Others stated that, in other Federal court decisions on Title VII and Title IX, the text of the Title IX statute and regulation are held to be ''at least susceptible to'' the interpretation that it prohibits anti-transgender bias.[115]

Other commenters disagreed, stating that the courts are not unanimous on the question and pointed to legal precedent saying that gender identity is not encompassed by sex discrimination under Federal civil rights statutes. Commenters stated that the 2016 Rule had departed from existing civil rights law by creating new prohibited conduct unsupported by the text of the statutes. Commenters stated that Title IX has been interpreted by the courts for decades to apply to biological women.[116] Other commenters stated that the fact that the Supreme Court has agreed to consider the legality of the general theory proposed in the 2016 Rule demonstrates it is a novel and contested legal issue.[117] Other commenters stated Congress clearly intended ''sex discrimination'' to be defined with reference to biological classification as male or female, and that is the only understanding that is reasonably supported by the text, history, or structure of the relevant law. Some criticized the 2016 Rule's reliance on the EEOC's opinion in *Macy* v. *Holder,* 2012 EEOPUB LEXIS 1181, 112 FEOR (LRP) 257 (2012) (Title VII).

Response: The Department disagrees with commenters who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination. Some of the cases referenced by such commenters were decided under the Equal Protection Clause of the Constitution,[118] under which courts have applied intermediate levels of scrutiny, permitting governments to adopt ''discriminatory means'' on the basis of sex only insofar as those means are substantially related to the achievement of important governmental objectives and are not ''used to create or perpetuate the legal, social, and economic inferiority of women.'' [119] The Department does not agree that the Equal Protection cases cited by these commenters require Title IX to include a prohibition on gender identity discrimination. Unlike the Equal Protection Clause, Title VII and Title IX broadly forbid covered entities from discriminating on the basis of sex, with limited exemptions expressly provided in statute. Title VII exempts covered entities from the prohibition on sex discrimination where sex is a ''bona fide occupational qualification.'' [120] Title IX exempts covered entities from the prohibition on sex discrimination for admissions to historically single-sex colleges, school father-son and mother-daughter activities (so long as reasonably comparable activities are provided for students of both sexes), beauty pageants, certain boys' or girls' conferences, single-sex voluntary youth service organizations, fraternities and sororities, and military training programs.[121]

The text of Title IX also demonstrates that it is not susceptible to an interpretation under which it would prohibit gender identity discrimination. The statute permits covered entities to maintain ''separate living facilities for the different sexes,'' and it expressly presents this, not as an exemption from the nondiscrimination requirements, but as an ''interpretation'' of them: Separate-sex living facilities are not, as such, discriminatory.[122] The Department's Title IX regulations likewise permit separate-sex housing, intimate facilities, physical education and human sexuality courses, and contact sports.[123] The statute presents these distinctions as being fully compatible with its nondiscrimination requirement. Nondiscrimination requires that separate-sex facilities and programs be (where relevant) comparable to one another, but the existence of separate-sex facilities and programs is not, as such, discriminatory under Title IX. Consequently, the Department does not believe an interpretation of Title IX that would prohibit gender identity discrimination is compatible with the statute's overall approach towards what

[111] 84 FR 27872 (''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, letters, and the preamble to [the 2016 Rule]) that is 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.'').

[112] ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' Exec. Order No. 13891, 84 FR 55235 (Oct. 9, 2019).

[113] 81 FR 31387–88, 31467.

[114] 81 FR 31471.

[115] *See G.G. ex rel. Grimm* v. *Gloucester Cty. Sch. Bd.,* 822 F.3d 709 (4th Cir. 2016), *recalling mandate & issuing stay,* 136 S. Ct. 2442 (2016).

[116] *See, e.g., N. Haven Bd. of Ed.* v. *Bell,* 456 U.S. 512, 517–20, (1982); *Cannon* v. *Univ. of Chi.,* 441 U.S. 677, 680 (1979).

[117] Order, *R.G. & G.R. Harris Funeral Homes* v. *EEOC,* No. 18–107 (U.S. Apr. 22, 2019) (granting certiorari).

[118] *See Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011).

[119] *United States* v. *Virginia,* 518 U.S. 515, 516 (1996).

[120] 42 U.S.C. 2000e–2(e)(1).

[121] 20 U.S.C. 1681.

[122] 20 U.S.C. 1686.

[123] 45 CFR 86.32–34, § 86.41.

does and does not constitute sex discrimination.

Case law under both Title VII and Title IX has likewise recognized that these statutes do not forbid reasonable and relevant distinctions between the sexes.[124] As the United States Solicitor General recently put it, ''Many commonplace practices that distinguish between the sexes do not violate [Title VII] because they account for real physiological differences between the sexes without treating either sex less favorably.'' [125] No express statutory carve-out is required in order for employers under Title VII to be permitted to impose a sex-specific dress code that burdens men and women equally, nor in order for educational institutions under Title IX to be permitted to require men and women to shower separately from each other. And as compared to the fields of employment and of education, the field of healthcare necessarily may contain many more ''commonplace practices that distinguish between the sexes . . . [by] account[ing] for real physiological differences between the sexes without treating either sex less favorably.'' As discussed in greater detail later in the subsection of this preamble on gender identity, reasonable distinctions between the sexes may be called for in numerous areas within the Department's expertise, including shared hospital rooms,[126] sex-specific protections for patients' modesty,[127] specialized medical practices related to gynecology,[128] and medical treatments or recommendations relying on sex-based generalizations,[129] and other research situations.[130] The biological differences between men and women are not irrelevant to employment law and education, and they are in many ways even more relevant in the health setting.

In general, a covered entity is permitted to make distinctions on the basis of sex that are ''not marked by misconception and prejudice, nor . . . show disrespect for either class.'' [131] In many cases, removing or weakening such reasonable sex-based distinctions could undermine the equality of the sexes by disproportionately harming women.[132] As discussed further below, case law is still developing as to whether covered entities' refusal to draw these distinctions could in some cases violate personal privacy interests and so create a hostile environment under Title IX.[133] ''[N]eutral terms can mask discrimination that is unlawful,'' while ''gender specific terms can mark a permissible distinction.'' [134] Where the ''[p]hysical differences between men and women'' are relevant, sex-neutral policies will in some cases ''undoubtedly require alterations'' to make them sex-specific, in order ''to afford members of each sex privacy from the other sex in living arrangements.'' [135]

Comment: Commenters stated that *Price Waterhouse* v. *Hopkins,* 490 U.S. 228 (1989), and *Oncale* v. *Sundowner Offshore Oil Services, Inc.,* 523 U.S. 75 (1998), fully support or even require the 2016 Rule's gender identity provisions or their equivalent. Commenters asked the Department to address specific court cases that they stated were contrary to the Department's view, such as *Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518 (3d Cir. 2018), *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017), and *Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011).

Response: For most of the history of Title IX case law, the ''commonplace practices that . . . account for real physiological differences between the sexes without treating either sex less favorably'' [136] were uncontroversial and not considered discriminatory. In the past five years, two circuit courts have begun to question this long-standing precedent in proceedings arising from motions for preliminary injunctions, although no circuit court has yet done so in a final ruling.[137]

These courts (and some district courts) draw on the Supreme Court's reasoning in *Price Waterhouse* in order to assert that otherwise permissible distinctions on the basis of sex must be applied (if at all) on the basis of an individual's subjective gender identity. But the novel legal theory advanced by these courts represents a serious misreading of *Price Waterhouse* and of Title IX, a reading that has been disputed by the decisions of other courts, including *Franciscan Alliance.*

Price Waterhouse is a Title VII case and establishes that, '' '[i]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes.' '' [138]

When courts have read *Price Waterhouse* as determining that ''on the basis of sex'' encompasses gender identity, they have done so on the ground that discrimination on the basis of gender identity is, as such, a form of sex stereotyping. But *Price Waterhouse* should be read in light of the Supreme Court definition of a ''stereotype'' about sex ''as a frame of mind resulting from

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[124] *See Wittmer* v. *Phillips 66 Co.,* 915 F.3d 328, 334 (5th Cir. 2019) (Ho, J., concurring); *Jespersen* v. *Harrah's Operating Co.,* 444 F.3d 1104, 1109–10 (9th Cir. 2006) (en banc) (collecting cases).

[125] Brief for EEOC, *R.G. & G.R. Harris Funeral Homes* v. *EEOC,* No. 18–107 (U.S. filed Aug. 16, 2019), at 36.

[126] *See Cypress* v. *Newport News General and Nonsectarian Hospital Association,* 375 F.2d 648, 658 (4th Cir. 1967) (''Our holding is simply that race cannot be a factor in the admission, assignment, classification, or treatment of patients in an institution like this, which is state-supported and receives federal funds. Room assignments may be made with due regard to sex, age, type of illness, or other relevant factors, but racial distinctions are impermissible, since the law forbids the treatment of individuals differently or separately because of their race, color, or national origin.''); *cf.* similar statutory requirements at 10 U.S.C. 4319 (Army), 10 U.S.C. 6931 (Navy), and 10 U.S.C. * 9319 (Air Force) (requiring separation of sleeping and latrine areas for ''male'' and ''female'' recruits); 10 U.S.C. 4320 (Army), 10 U.S.C. 6932 (Navy), and 10 U.S.C. 9320 (Air Force) (limiting after-hours access by drill sergeants and training personnel to persons of the ''same sex as the recruits'').

[127] *See, e.g.,* OCR Voluntary Resolution Agreement with Michigan State University, *https://cms-drupal-hhs-prod.cloud.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf,* at IV.D.1.d.iii, IV.D.1.d.v.

[128] *See, e.g.,* Women's Preventive Services Guidelines, Health Resources and Services Administration, Dec. 17, 2019 (HRSA) *https://www.hrsa.gov/womens-guidelines-2019.*

[129] *See* the Department's Office of Women's Health, *https://www.womenshealth.gov/.*

[130] *See* NIH 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*; NIH, Office of Research on Women's Health, ''Sex & Gender,'' *https://orwh.od.nih.gov/.*

[131] *See Tuan Anh Nguyen* v. *INS,* 533 U.S. 73.

[132] *See* Brief for EEOC, *Harris Funeral Homes,* at 37–38 (citing cases).

[133] *See, e.g., Doe* v. *Luzerne Cty.,* 660 F.3d 169, 176–77 (3d Cir. 2011) (recognizing that an individual has ''a constitutionally protected privacy interest in his or her partially clothed body'' and that this ''reasonable expectation of privacy'' exists ''particularly while in the presence of members of the opposite sex''); *Brannum* v. *Overton Cty. Sch. Bd.,* 516 F.3d 489, 494 (6th Cir. 2008) (''the constitutional right to privacy . . . includes the right to shield one's body from exposure to viewing by the opposite sex''); *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.''). *But see Parents for Privacy* v. *Barr,* No. 18–35708, (9th Cir. Feb. 12, 2020) (no title IX or constitutional privacy violation for school policy allowing student to use bathroom and locker rooms consistent with their gender identity).

[134] *Tuan Anh Nguyen* v. *INS,* 533 U.S. 64.

[135] *United States* v. *Virginia,* 518 U.S. 515, 550 n.19 (1996) (emphasis added) (brackets and citation omitted).

[136] Brief for EEOC, *Harris Funeral Homes,* at 36.

[137] *Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1039 (7th Cir. 2017); *Dodds* v. *United States Dep't of Educ.,* 845 F.3d 217 (6th Cir. 2016). The ruling in a third related case, *G.G.* v. *Gloucester Co. Sch. Bd.,* 822 F.3d 709 (4th Cir. 2016), was based on *Auer* deference to Department of Education subregulatory guidance and has since been vacated after that guidance was withdrawn.

[138] *Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 251 (1989), quoting *Los Angeles Dept. of Water & Power* v. *Manhart,* 435 U. S. 702, 707, n. 13 (1978).

irrational or uncritical analysis.'' [139] Wherever ''stereotyping play[s] a motivating role in an employment decision,'' according to *Price Waterhouse,* the employer has demonstrated an ''impermissible motive,'' for stereotypes should not even ''play a part in the decisionmaking process.'' [140]

The Department believes that, unlike stereotypes, reasonable distinctions on the basis of sex, as the biological binary of male and female, may, and often must, ''play a part in the decisionmaking process''—especially in the field of health services. A covered entity such as a healthcare provider is not impermissibly stereotyping biological males (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as ''him''; limits access to lactation rooms and gynecological practices to female users and patients; or lists a male's sex as ''male'' on medical forms. Similarly, a covered health care entity is not impermissibly stereotyping biological females (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as ''her''; warns females that heart-attack symptoms are likely to be quite different than those a man may experience; advises women that certain medications tend to affect women differently than men; or lists a female's sex as ''female'' on medical forms. Finally, it is not stereotyping for covered entities to have bathrooms or changing rooms designated by reference to sex, or to group patients in shared hospital rooms by sex.[141] Such practices and actions are not rooted in stereotypes, but in real biological or physiological differences between the sexes. Moreover, none of these examples disadvantages one sex over another, and in fact the failure to take sex into account may in some cases have a disadvantageous effect.

As the Supreme Court has noted, ''to fail to acknowledge even our most basic biological differences . . . risks making the guarantee of equal protection superficial, and so disserving it. Mechanistic classification of all our differences as stereotypes would operate to obscure those misconceptions and prejudices that are real.'' [142] ''[T]here is nothing irrational or improper in the recognition'' of the social and other consequences of real physiological differences between the sexes; ''[t]his is not a stereotype.'' [143] Reasonable distinctions ''may be based on real differences between the sexes . . . so long as the distinctions are not based on stereotyped or generalized perceptions of differences.'' [144] ''Prohibition of harassment on the basis of sex requires neither asexuality nor androgyny.'' [145]

Justice Ginsburg's majority opinion in *U.S.* v. *Virginia* sharply distinguished sex from other protected classes in this regard: ''Supposed 'inherent differences' are no longer accepted as a ground for race or national origin classifications. Physical differences between men and women, however, are enduring: '[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.' . . . 'Inherent differences' between men and women, we have come to appreciate, remain cause for celebration.'' [146] This recognition of physical (*i.e.,* biological) differences between men and women is not stereotyping and in some cases will ''undoubtedly require alterations'' to accommodated sex-specific differences.[147]

The lower court decisions referenced by commenters held that a covered entity which required transgender individuals to abide by otherwise permissible distinctions on the basis of sex, such as separate-sex bathrooms, would be impermissibly ''imposing its stereotypical notions of how sexual organs and gender identity ought to align.'' [148] A few lower courts have relied on these holdings in interpreting Section 1557 to require covered entities to override these reasonable distinctions based on sex, in deference to an individual's gender identity.[149] The notion that such distinctions on the basis of sex amount, as such, to impermissible stereotyping, would be lethal to countless reasonable and fully permissible healthcare practices, some of which have been identified above. No court has gone so far: These lower courts have questioned such distinctions only insofar as these distinctions come into conflict with an individual's stated gender identity. But *Price Waterhouse* offers no basis for this regime of individualized exceptions to otherwise reasonable distinctions. If it is impermissible stereotyping of a female employee to demand that she not ''behave aggressively,'' then *Price Waterhouse* (to the extent that it applies) requires companies to stop holding *all* female employees to such a stereotyped standard—not merely to grant exceptions for the occasional female employee who objects to that standard.[150] Similarly, if it is impermissible stereotyping to assume that ''sexual organs . . . ought to align'' with the sex listed on one's hospital bracelet, then *Price Waterhouse* (to the extent that it applies) would invalidate the existence of *all* sex markers on hospital bracelets, not merely of those to which a transgender individual has objected. Where a covered entity has not stereotyped but has only drawn a reasonable distinction, *Price Waterhouse* is irrelevant.

Distinctions based on real differences between men and women do not turn into discrimination merely because an individual objects to those distinctions. Title IX does not require covered entities to eliminate reasonable distinctions on the basis of sex whenever an individual identifies with the other sex, or with no sex at all, or with some combination of the two sexes

[139] *Tuan Anh Nguyen* v. *I.N.S.,* 533 U.S. 53, 68 (2001).

[140] *Price Waterhouse,* 490 U.S. 252–53, 254–55. The Civil Rights Act of 1991 amends the *Price Waterhouse* standard to say that ''an unlawful employment practice is established when the complaining party demonstrates that . . . sex . . . was a motivating factor for any employment practice, even though other factors also motivated the practice,'' but the employer may rebut this claim if he or she ''demonstrates that [the employer] would have taken the same action in the absence of the impermissible motivating factor.'' 42 U.S.C. 2000e–2(m), § 2000e–5(g)(2)(B).

[141] *See* 29 CFR 1910.141(c) (OSHA regulation requiring ''toilet rooms separate for each sex'').

[142] *Tuan Anh Nguyen,* 533 U.S. at 73. In *Sessions* v. *Morales-Santana,* 137 S. Ct. 1678 (2017), the Supreme Court struck down, on intermediate-scrutiny grounds, a statute that granted U.S. citizenship to children born abroad of unwed parents if the child's mother had been a U.S. citizen for one year before the birth, but required five years in the case of a U.S. citizen father. However, the Court did not reject the *Nguyen* analysis recognizing that sex distinctions are real, and that not all such distinctions are based on unlawful stereotypes.

[143] *Id.* at 68.

[144] *Faulkner* v. *Jones,* 10 F.3d 226, 232 (4th Cir. 1993).

[145] *Oncale* v. *Sundowner Offshore Oil Services, Inc.,* 523 U.S. 75, 81 (1998).

[146] *United States* v. *Virginia,* 518 U.S. 515, 533 (1996) (internal citations omitted).

[147] *Id.* at 550 n.19.

[148] *Equal Employment Opportunity Comm'n* v. *R.G. &. G.R. Harris Funeral Homes, Inc.,* 884 F.3d 560, 576 (6th Cir. 2018). *See also Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1051 (7th Cir. 2017) (''the School District treats transgender students like Ash, who fail to conform to the sex-based stereotypes associated with their assigned sex at birth, differently. These students are disciplined under the School District's bathroom policy if they choose to use a bathroom that conforms to their gender identity.''); *Glenn* v. *Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011) (''A person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes.'').

[149] *See Rumble* v. *Fairview Health Servs.,* No. 14–cv–037 (SRN/FLN), 2017 WL 401940 (D. Minn. Jan. 30, 2017); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017)

[150] *See Price Waterhouse,* 490 U.S. at 235, 250–51.

(as under the 2016 Rule).[151] Rather, Title IX prohibits subjecting a person to less favorable treatment because of his or her sex. Thus, if a person claims to have been discriminated against on the basis of his or her sex, that claim is neither weakened nor strengthened by any allegations about his or her ''internal sense of gender.'' Numerous lower courts have held that, like any other man or woman, a transgender individual may sue under Title VII if he or she is harassed, assaulted, terminated, or otherwise discriminated against because of his or her sex.[152] Under Title IX, as under Title VII, ''[t]ranssexuals are not genderless, they are either male or female and are thus protected under Title VII to the extent that they are discriminated against on the basis of sex.'' [153] The Department will vigorously enforce Section 1557's prohibition on sex-based discrimination, but that prohibition cannot be construed as a prohibition on reasonable sex-based distinctions in the health field.

Comment: Commenters offered a variety of views on the role that a patient's sex and/or gender identity ought to play in medical decision-making.

Many commenters spoke of the importance of sex-reassignment surgeries and cited studies that they said show the value of these surgeries in alleviating gender dysphoria. Others cited different studies that they said show the opposite. Some clinicians expressed concerns about consent and medical appropriateness of pre-pubertal sex reassignment with lifelong physical and mental implications (including permanent sterility) when children and adolescents lack the requisite social, emotional, and intellectual maturity, or life experiences necessary for true consent. Commenters also were concerned about coercive, peer, adult, and ideological pressures on children and adolescents to seek cross-sex hormonal treatment, sex reassignment surgery, or other similar services. Some commenters, including parties to lawsuits against the Department on the ground that the 2016 Rule would require gender transition treatments and therapies for children, criticized the 2016 Rule for containing no age limitation. Commenters stated that the ''gender-affirming'' model is the most controversial form of counseling and, as such, is not used by the Dutch national transgender clinic, which they said is considered the international flagship of gender dysphoria treatment.

Some commenters noted that violations of the 2016 Rule are enforceable by termination of Federal financial assistance and that violations of State law with respect to healthcare may involve civil penalties for negligence or malpractice, etc. In light of this, they stated that the 2016 Rule placed providers in an impossible position, where compliance with one law means noncompliance with another, and either choice results in a steep penalty.

Other commenters said that the 2016 Rule's definition of ''on the basis of sex'' could prohibit the way OB/GYN practices specialize in treating females, and raised the concern that specializing in the treatment of female patients could be deemed prohibited discrimination against biological males who identify as women. Commenters stated that because these services are focused on and tailored to females as a single biological sex, they are able to provide a higher quality of care to those patients. They noted that it has long been a permissible sex-based distinction for OB/GYN doctors to not treat any biological males, and this distinction is recognized under HHS Title IX regulations. Such commenters found the 2016 Rule overbroad and inconsistent with day-to-day affairs in how they practice medicine. But other commenters stated that OB/GYNs are not affected by the transgender requirements under the 2016 Rule and that pre-existing OB/GYN practices are justified by reasonable scientific justifications.

Certain providers advocated for removal of the requirement to ''treat individuals consistent with their gender identity,'' as this provision would violate the conscience rights of healthcare providers, and the ethical and foundational convictions that underlie the entire way they practice medicine. Other commenters said that repeal of this provision leaves no clarity about whether such providers will actually provide treatment for transgender patients, and expressed the concern that affirming treatment consistent with gender identity is necessary for high-value transgender healthcare, as is required for all people in the practice of medicine.

Some commenters noted their concern that the 2016 Rule requires doctors to remove healthy reproductive tissue in sex-reassignment surgeries, even if it may be contrary to the patient's medical interest. For example, if a surgeon performs mastectomies as part of a medically necessary treatment for breast cancer, under the 2016 Rule, he or she could also have been required to perform mastectomies for sex-reassignment purposes when recommended by a psychologist, even if the surgeon believes such treatments are not medically indicated in his or her own professional judgment. Similarly, commentators argued that some doctors might be forced to perform hysterectomies not only against their medical judgment but also outside of their expertise. Other commenters contended that certain procedures are not meaningfully different when performed on a transgender versus non-transgender patient, because the mechanics of the procedures are substantially similar. Although genital reassignment surgery is considered a ''gender transition service,'' clinicians commented that somewhat similar procedures are used for genital reconstruction to repair damaged, diseased, or disfigured genital tissue, or in the treatment of disorders of sexual development.

Commenters also stated that the 2016 Rule would force them to provide services damaging to the health of patients, in conflict with their mission as a healthcare provider, instead of using these medical resources to help patients.[154]

Commenters stated that HHS does not have a compelling interest in requiring the medical provision of, or insurance

[151] *See Johnston* v. *Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ.,* 97 F. Supp. 3d 657 (W.D. Pa. 2015).

[152] *Barnes* v. *City of Cincinnati,* 401 F.3d 729 (6th Cir. 2005); *Smith* v. *City of Salem,* 378 F.3d 566 (6th Cir. 2004). These cases have been cited, by the 2016 Rule and in some recent court cases, in support of the view that sex discrimination encompasses discrimination on the basis of gender identity. This is a serious misreading pointed out at *Johnston* v. *Univ. of Pittsburgh of Com. Sys. of Higher Educ.,* 97 F. Supp. 3d 657, 675n17 (W.D. Pa. 2015) (''In *Smith* v. *City of Salem,* . . . the court did not conclude that ''transgender'' is a protected class under Title VII, but only that a male or female who is also transgender can assert a sex stereotyping claim under Title VII for adverse employment actions that result from the individual's conformity to their gender identity rather than their biological or birth sex. Indeed, the same year that the 6th Circuit issued its opinion in *Smith,* it affirmed, in an unpublished opinion, a district court decision holding that ''Title VII does not prohibit discrimination based on an individual's status as a transsexual,'' in an employment discrimination case involving a transgender women's use of a men's restroom. *Johnson* v. *Fresh Mark, Inc.,* 98 Fed. App'x. 461, 462 (6th Cir.2004).'').

[153] *Tronetti* v. *TLC HealthNet Lakeshore Hosp.,* No. 03–CV–0375E(SC), 2003 WL 22757935, at *4 (W.D.N.Y. Sept. 26, 2003). *See Rosa* v. *Park West Bank Trust Co.,* 214 F.3d 213, 215–16 (1st Cir. 2000) (discrimination against a cross-dressing man is sex-based discrimination if the entity would have treated a ''similarly situated'' woman differently, *i.e.,* if it treats ''a woman who dresses like a man differently than a man who dresses like a woman'').

[154] Commenters cited specific examples of coercion. *See Minton* v. *Dignity Health,* 2017 WL 7733922 (Cal. Super. Ct. Nov. 2017); *Robinson* v. *Dignity Health,* No. 16–cv–3035 YGR, 2016 WL 7102832 (N.D. Cal. Dec. 6, 2016) (on remand from U.S. Supreme Court).

for, gender transition services or procedures. Other commenters stated that access to such services for transgender patients constitutes a compelling interest. Some commenters challenged the idea that an individual born as one biological sex can in actuality be transformed into a person of the other sex, with or without surgeries or hormone treatments.

Response: The Department recognizes that certain single-sex medical procedures, treatments, or specializations are rooted in the binary and biological meaning of sex for valid scientific and medical reasons. The Department believes the 2016 Rule caused significant confusion and cast doubt as to whether such longstanding specialized practices remained lawful, as indicated, for example, by the fact that commenters had diverging views on how the 2016 Rule impacted OB/GYN practices. The Department declines to interfere in these practices, and repeals a mandate that was, at least, ambiguous and confusing.

The Department appreciates the many comments received on the issue of gender identity, gender dysphoria, and the appropriate care for individuals with gender dysphoria. The Department believes providers should be generally free to use their best medical judgment, consistent with their understanding of medical ethics, in providing healthcare to Americans. The wide variation in these comments confirms that the medical community is divided on many issues related to gender identity, including the value of various ''gender-affirming'' treatments for gender dysphoria (especially for minors), the relative importance of care based on the patient's sex, and the compatibility of gynecological practice with a requirement of nondiscrimination on the basis of gender identity.[155]

The Department is also reluctant to pretermit ongoing medical debate and study about the medical necessity of gender transition treatments. The 2016 Rule assumed that, if a covered entity offers a ''categorical coverage exclusion or limitation for all health services related to gender transition,'' then that entity must be relying on medical judgments that are ''outdated and not based on current standards of care.'' [156] But based on its review of the most recent evidence, the Department concludes that this was an erroneous assertion, and that there is, at a minimum, a lack of scientific and medical consensus to support this assertion, as the comments noted above demonstrate. This lack of scientific and medical consensus—and the lack of high-quality scientific evidence supporting such treatments—is borne out by other evidence. For example, on August 30, 2016, CMS declined to issue a National Coverage Determination (NCD) on sex-reassignment surgery for Medicare beneficiaries with gender dysphoria ''because the clinical evidence is inconclusive.'' [157] CMS determined, ''[b]ased on an extensive assessment of the clinical evidence,'' that ''there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.'' [158] Similarly, in a 2018 Department of Defense (DOD) report on the diagnosis of gender dysphoria, which included input from both transgender individuals and medical professionals with experience in the care and treatment of individuals with gender dysphoria, DOD found that there is ''considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.'' [159] Other research has found that children who socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood.[160] The Department does not believe that the nondiscrimination requirements in Title IX, incorporated by reference into Section 1557, foreclose medical study or debate on these issues. And to the extent that a medical consensus develops on these issues, it is not clear that regulations of the sort encompassed in the 2016 Rule would be necessary to encourage medical professionals to follow such consensus.

The Department believes that its approach in the 2016 Rule inappropriately interfered with the ethical and medical judgment of health professionals. The preamble to the 2016 Rule stated that, under that Rule, ''a provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.'' [161] This statement raised the prospect of forcing a provider to perform irreversible, sterilizing, and endocrine-disrupting procedures on what may be, in the provider's view, non-diseased and properly functioning organs—including in children and youth.[162] A medical provider may rightly judge a hysterectomy due to the presence of malignant tumors to be different in kind from the removal of properly functioning and healthy reproductive tissue for psychological reasons, even if the instruments used are identical. For example, OB/GYNs competent and willing to perform dilation and curettage procedures to aid with recovery from a miscarriage should not, and legally cannot,[163] be forced to perform dilation and curettage procedures for abortions, because the regulatory, ethical, and medical frameworks that apply to abortions are radically different from those that apply to recovery from miscarriages. Moreover, commenters who offer transition services made clear that these often involve specialized cross-sex hormonal treatments before and after any sex-reassignment surgeries, and require coordination of care with urologists, psychiatrists, and a variety of other healthcare professionals in different specialized fields. A provider who routinely provides, for example, hysterectomies to address uterine cancer should be able reasonably to choose not to be involved in what may be the much more medically complicated set of procedures involved in sex reassignment.

[155] Comments referring specifically to providers' conscientious objections to certain forms of treatment are addressed below in the section on ''relation to other laws.''

[156] *Cf.* 81 FR 31472, 31429.

[157] CMS, ''Decision Memo for Gender Dysphoria and Gender Reassignment Surgery'' (CAG–00446N) (Aug. 30, 2016) *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282.*

[158] *Id.*

[159] Department of Defense, ''Report and Recommendations on Military Service by Transgender Persons'' (Feb. 22, 2018), 5.

[160] Thomas D. Steensma, Ph.D., Jenifer K. McGuire, Ph.D. M.P.H., et al. ''Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study,'' 52(6) Journal of the American Academy of Child & Adolescent Psychiatry 582–90 (2013).

[161] 81 FR 31455.

[162] In this regard, the Department distinguishes between the situation created by the requirements of 2016 Rule and the in-program requirements applied within federally funded grant programs where, for example, ''the general rule that the Government may choose not to subsidize speech applies with full force,'' even if the speech concerns what is allegedly required by medical ethics. *See, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 200 (1991).

[163] *See* Church Amendments, 42 U.S.C. 300a–7.

Upon reconsidering this issue, the Department now believes that the 2016 Rule did not offer a sufficient analysis to justify the serious effect of requiring providers to perform certain procedures or provide certain treatments contrary to their medical judgment. The Department does not and need not take a definitive view on any of the medical questions raised in these comments about treatments for gender dysphoria. The question is whether Title IX and Section 1557 require healthcare professionals, as a matter of nondiscrimination, to perform such procedures or provide such treatments. The answer is that they do not. This final rule does not presume to dictate to medical providers the degree to which sex matters in medical decision making, nor does it impose the 2016 Rule's vague and overbroad mandate that they ''treat individuals consistent with their gender identity.''

Nothing in this final rule prohibits a healthcare provider from offering or performing sex-reassignment treatments and surgeries, or an insurer from covering such treatments and procedures, either as a general matter or on a case-by-case basis. The large number of comments received from healthcare providers who perform such treatments and procedures suggests that there is no shortage of providers willing to do so, even without the 2016 Rule's provisions on gender identity (which had been enjoined for over two years by the time of the comment period).

Finally, the *Franciscan Alliance* court held that HHS had not demonstrated a compelling interest in requiring providers with sincerely held religious objections to gender transition services, notwithstanding their objections, to provide these services. The Department sees no compelling interest in forcing the provision, or coverage, of these medically controversial services by covered entities, much less in doing so without a statutory basis.

Comment: Some commenters stated that revising the rule to eliminate the court-vacated provisions on gender identity, in conjunction with other Federal actions related to gender transition-related services, is evidence of animus to transgender individuals, and that the free exercise of religion or conscience claims raised by medical professionals and insurers are merely ''pretext'' for invidious discrimination. Others contended that the proposed rule recognizes the human dignity of all because certain surgical procedures and medications related to gender identity and abortion do not actually serve the health or wellbeing of patients but violate their dignity and physical and psychological integrity, especially of children and women in crisis pregnancies, and that these providers act out of sincere beliefs both as to medical judgment and religious belief in pursuing the best interests of patients regardless of their background or stated identities.

Response: The Department respects the dignity of all individuals. It seeks to further the health and well-being of all, but it can do so only by implementing the laws as adopted by Congress.

Moreover, the Department notes that commenters have provided a number of bases for objections to being forced to provide or cover certain treatments or surgeries contrary to their sincere medical, economic, religious, scientific, ethical, or conscience-based reasons. To presume that religious beliefs on these issues are rooted in bigotry, animosity, or insincerity would risk unlawfully stereotyping people of faith. *See Masterpiece Cakeshop* v. *Colorado Civil Rights Comm'n,* 138 S. Ct. 1719, 1729 (2018) (''To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: By describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.'').[164]

Comment: Commenters expressed various views on whether transgender patients should be treated in accord with their expressed gender identity and/or in accord with their sex.

Some commenters stated that transgender designations conceal real biological sex differences that are relevant to medical risk factors, recognition of which is important for effective diagnosis, treatment, and disease prevention—including effective treatment for patients who identify as transgender. Some added that biological sex differences remain present in numerous bodily systems even after a patient has undergone hormonal and/or surgical transition therapies, and that physicians must be permitted to take these differences into account. Healthcare providers commented that critical decisions are made in the practice of medicine on the basis of objective biological information concerning a person's sex as being male or female because, among other reasons, medications and treatments affect males and females differently, and only females can become pregnant, regardless of stated gender identity. These commenters were concerned that by requiring providers to treat patients consistent with gender identity instead of biological sex, the patients' health is endangered, with both short- and long-term consequences.[165]

Other commenters stated that the Department has not provided sufficient explanation or justification for removing § 92.206 of the 2016 Rule with respect to ensuring equal access to healthcare services without respect to sex, including prohibitions on discriminatory denials of services typically associated with one sex to persons who identify as transgender. The commenters stated that the Department ignored the text of § 92.206 when it asserted in the proposed rule that the 2016 Rule would ''require[e] healthcare entities to code as male all persons who self-identify as male, regardless of biology, [which] may lead to adverse health consequences.'' [166] Commenters said § 92.206 properly prohibits, among other things, the arbitrary denial of care based not on clinical considerations but solely on the patient's ''sex as assigned at birth'' or as recorded in medical or insurance records. Others said that while the biological definition of ''sex'' may be appropriate for scientific contexts such as National Institutes of Health (''NIH'') studies, the Department's nondiscrimination provisions should define the term more broadly.

Some commenters commented on a case of a transgender patient with abdominal pains who, as a result of being treated according to a male gender identity, was not diagnosed as being pregnant as part of the triage process and had a stillborn child. Some commenters viewed this set of facts as evidence against the 2016 Rule while others claimed it was evidence for the 2016 Rule.

Response: The Department has long recognized that the practice of medicine and biomedical research routinely involves decisions and diagnoses that legitimately make distinctions based on sex, including decisions made at triage; research studies (including clinical trials); questions of medical history; and requests for a medical consultation. As discussed at length in the NPRM, substantial scientific literature published after the 2016 Rule indicates that sex-specific practices in medicine and research exist because biological

[164] Religious exemptions will be addressed further in the section discussing the final rule's relation to other laws.

[165] Commenters cited texts including William J. Malone, MD, Gender Dysphoria Resource for Providers (3rd Edition); and Michael Laidlaw, MD, ''The Gender Identity Phantom,'' International Discussion Space for Clinicians and Researchers (Oct. 24, 2018) *http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom.*

[166] *See* 84 FR 27885, n. 55.

(and, derivatively, genetic) differences between males and females are real and matter to health outcomes and research.[167] For example, 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.'' [168] 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 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.[169]

Yet the 2016 Rule required covered entities to ''treat individuals consistent with their gender identity'' in virtually every respect. The 2016 Rule's definition of gender identity does not turn on any biological or external indicia of sex, and explicitly disavows any such reliance.[170] Under the 2016 Rule, one can identify as ''male, female, neither, or a combination of male and female.'' A person's gender identity under the 2016 Rule is determined ultimately by what a person says his or her gender identity is, and a covered entity is bound to treat all individuals ''consistent with their gender identity'' the moment it becomes aware of such a declaration (which must be allowed to change under the 2016 Rule). No other Federal statute, agency rule, or guidance has ever gone so far on this question.[171]

In this regard, the 2016 Rule risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity. By eliminating the transgender provisions and definitions from the 2016 Rule, this final rule clarifies that sex, according to the Title IX's plain meaning, may be taken into account in the provision of healthcare, insurance (including insurance coverage), and health research, as was the practice before the 2016 Rule.

Section 92.206 of the 2016 Rule required covered entities to ''treat individuals consistent with their gender identity'' in every respect save one. Namely, ''a covered entity 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.'' This confusingly worded exception is premised on the fact that entities may provide specific services to ''one sex'' based on biology, yet must grant transgender individuals access to such single-sex services regardless of how they identify *and* regardless of their sex (''sex assigned at birth''). The 2016 Rule's mandate cannot answer, for example, how a provider is to determine whether or when a transgender individual is entitled by law to be referred to a women's mental health support group, a men's mental health support group, either group, or both at the same time.

Some providers choose to code and track patients according to their biology for some purposes and according to their gender identity for other purposes. Under the 2016 Rule, however, if a transgender patient self-identifies as male in the medical intake process, yet an examining doctor has reason to believe the patient is biologically female, the doctor could reasonably assume that he or she is *prohibited* from changing the person's chart to reflect female sex, because that would not be treating the person ''consistent with'' her stated gender identity.

In the 2019 NPRM, the Department cited a 2019 case from a medical journal article that concluded that a nurse had applied longstanding standards when triaging what the article called a ''man with abdominal pain,'' who identified as male and had been classified as such, but who was in fact a pregnant woman.[172] Because indications of pregnancy were not manifest, and because the patient was treated according to stated gender identity, her pregnancy was not diagnosed early, and the child was stillborn.

This provider was treating the patient according to her stated gender identity (male), just as the 2016 Rule demanded. Indeed, the provider risked liability under the 2016 Rule for not taking that step. The provider did not act unreasonably when, consistent with longstanding medical practice, it did not have a policy of asking every man with abdominal pain whether he is pregnant.

Unlike the many strained hypothetical objections offered in opposition to the proposed rule, this case is not based on speculation. Rather,

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[167] *See, e.g.,* NIH Research Matters, Gene Linked to Sex Differences in Autism (Apr. 14, 2020), *https://www.nih.gov/news-events/nih-research-matters/gene-linked-sex-differences-autism;* 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); Ramona Stone and W. Brent Weber, Male-Female Differences in the Prevalence of Non-Hodgkin Lymphoma, 81 Journal of Environmental Health 16 (Oct. 2018); *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''); 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); 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;* 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;* 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).

[168] 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.*

[169] Janine Austin Clayton (Office of Research on Women's Health, NIH), ''Applying the new SABV (sex as a biological variable) policy to research and clinical care.'' *Physiology & Behavior* 187 (2018), 2.

[170] 81 FR 31467 (''Gender identity means an individual's internal sense of gender'' whose expression ''may or may not conform to social stereotypes associated with a particular gender''); 81 FR 31468 (''[sex] 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.'') (emphasis added).

[171] *Cf.* 18 U.S.C. 249 (Shepard-Byrd Hate Crimes Act) (defining gender identity as ''actual or perceived gender-related characteristics'').

[172] *See* 84 FR 27855, n. 55, citing 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* (a patient with an electronic medical record classification as male did not receive care to treat ''labor, placental abruption, or preeclampsia—urgent conditions presenting a potential emergency'').

it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances, this story serves as an example of the consequences that could result from the confusion caused by the 2016 Rule and its mandate to treat individuals ''consistent with'' stated gender identity.

Comment: Commenters stated that it is clear that characteristics traditionally protected under antidiscrimination law are those inherent, immutable, and readily identifiable. They stated that a binary and biological definition of sex enables consistency and clarity about who is a member of the protected category, what the prohibited conduct is, how covered entities must comply both by inaction and action, and when government enforces a right against discrimination. Commenters stated that changing the definition of the protected category to an identity that is changeable and fluid results in a legal standard that is impractical if not impossible to apply to particular circumstances. Commenters found that those courts that recognize gender identity discrimination apply the prohibitions inconsistently.

Healthcare providers submitted comments stating that ''gender identity'' is a subjective psychological concept that cannot be anatomically located within the brain, and that no MRI or CT scan, autopsy, genetic testing, blood test, or pathology report can localize an ''internal sense'' and verify whether the gender identity of a patient is actually male, female, neither, or a combination of male or female.

Commenters stated that they did not understand the categories in the 2016 Rule's definition of gender identity which are not obviously limited in the number of possible permutations nor anchored in biology. Commenters were concerned that Title IX's prohibitions against disparate treatment of biological women as different from biological males may no longer be prohibited or even enforceable. When a protected category that was binary now becomes a subjective spectrum, commenters did not know what the substantive standard was to establish a facial violation, or how to apply it to particular facts. Some commenters stated that it contradicts Title IX to treat sex as a non-binary concept when the statute explicitly protects persons of either ''one sex'' or ''the other sex.'' Commenters stated the 2016 Rule retained the words male or female—two categories which have long formed the biological and binary concept of sex—but eliminated their substantive content. The breadth of the definition of gender identity included both exterior (''expression'') and interior (''internal'' sense) characteristics; mental (''identity'') and physical (''body characteristics''); variable over time (at birth vs. after birth), feminine or masculine (binary), both (''some combination''), and androgyny (''neither''). Commenters stated that they did not have clarity as to how to assess claims of ''either/or'' disparate treatment as well as ''both/and.'' Commenters also noted the text also included an expansive catchall provision stating that the definition of gender identity ''is not limited to'' what was in that enumerated list.

Response: The Department agrees that gender identity is difficult to define, in some cases difficult to categorize, and frequently very difficult to determine with objective certainty. For these and reasons stated elsewhere, the 2016 Rule's provisions on gender identity were confusing facially and in application. This final rule eliminates that confusion by returning to the plain meaning of the underlying statutes, relying as it does on the plain meaning of ''sex'' as biologically binary.

Comment: The Department received comments stating that the proposed rule would harm the privacy interests of children with gender dysphoria who seek to use restrooms according to gender identity and would otherwise encourage bullying. Commenters also alleged that in Federal court cases concerning gender identity unrelated to health services, courts have rejected arguments about competing privacy concerns of non-transgender individuals with respect to bathroom access for transgender individuals.

Response: These comments show that, although the preamble to the 2016 Rule had stated that it was not intended to overrule ''existing Federal, State and local laws, rules or regulations'' such as Title IX or its regulations, under which ''certain types of sex-specific facilities such as restrooms may be permitted'' such as bathrooms or intimate facilities,[173] even the 2016 Rule's supporters can reasonably interpret its provisions as doing precisely that.

The Department acknowledges that there is new and developing case law on the intersection of privacy concerns of non-transgender individuals and bathroom access for transgender individuals.[174] As commenters pointed out, there have been recent Title IX complaints regarding access to intimate facilities and associated case law. One complaint alleged a sexual assault by a male who identifies as female and had been granted access to a single-sex (female) facility based on stated gender identity.[175] Another incident involved dueling discrimination and privacy complaints concerning the use of communal shower facilities. After filing a complaint, a male who identifies as female was granted an exception to live as a female. A group of females filed complaints that their privacy rights were violated.[176] At least one Title IX complaint similar to these was denied by a court because of the specific facts of the case.[177] But the case law on such complaints is very new and still developing.

The Department notes that, regardless of whether Title IX *requires* covered entities to maintain sex-specific bathrooms, the Title IX regulations continue to *permit* policies that regulate intimate facilities based on sex. These regulations are consistent both with the ordinary, biological understanding of the word ''sex'' as reflected throughout the text of Title IX and the ordinary understanding of discrimination. Indeed, as the U.S. government has noted, the provisions in Title IX stating that nothing in that statute prohibits educational institutions from ''maintaining separate living facilities *for the different sexes*'' ''could not sensibly function if 'the term 'sex' includes 'gender identity,' which, unlike 'sex,' may not be limited to two categories.'' [178] Moreover, it has long been understood that, although ''separate bathrooms are obviously not blind to sex, they do not discriminate because of sex . . . so long as they do not treat men or women disadvantageously compared to the opposite sex.'' [179] In light of experience, including experience since the 2016 Rule was promulgated, the Department concludes that this final rule, by

[173] 81 FR 31409.

[174] *See, e.g., Soule* v. *Conn. Ass'n of Schools,* No. 3:20–cv–00201 (D. Conn. filed Feb. 12, 2020).

[175] Moriah Balingit, ''After Alleged Sexual Assault, Officials Open Investigation of Transgender Bathroom Policy,'' *The Washington Post* (Oct. 9, 2018), *https://www.washingtonpost.com/local/education/after-alleged-sexual-assault-officials-open-investigation-of-transgender-bathroom-policy/2018/10/09/431e7024-c7fd-11e8-9b1c-a90f1daae309_story.html.*

[176] *See* Department of Defense, ''Report and Recommendations,'' 37.

[177] *See Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518, 531–33 (3d Cir. 2018).

[178] Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

[179] Brief for EEOC, *Harris Funeral Homes,* at 36.

removing the possibility that the Section 1557 regulations could be read as overruling Title IX's regulatory permission to maintain certain sex-segregated facilities (a permission consonant with Title IX's prohibition on sex discrimination, as explained above), will better permit covered entities to balance relevant privacy interests. The Department declines to retain a provision that could reasonably be read to prohibit covered entities from recognizing the difference between men and women or acting to protect men's and women's privacy interests in HHS-funded health programs or activities.[180]

Comment: Some commenters challenged the requirement under the 2016 Rule that medical professionals must use a patient's preferred pronouns based entirely on self-identification, regardless of biological sex or the presence or absence of surgery or the use of masculinizing or feminizing hormone treatments. Some commenters disagreed with any requirement that forces providers to treat patients in a manner other than according to their biological sex, including through coerced use of pronouns. Others stated that social transition treatment required providers to use the preferred pronouns or preferred names of patients, and to identify patients according to their preferred sex effectively at all times.

Response: The 2016 Rule preamble held out a provider's ''persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth'' as a potential example of hostile-environment sex discrimination under Section 1557.[181] At least one district court has held similarly that when a provider allegedly ''continuously referred to'' a transgender patient ''with female pronouns'' in accordance with her sex, this could be sufficient grounds for a sex discrimination claim under Section 1557 in light of the *Price Waterhouse* ''stereotyping'' theory discussed above.[182] This view, again, rested on a misreading of Title IX.

Pronouns are not stereotypes. Pronouns reflect the most elementary sex-based classification in the English language. They are routinely used in scientific contexts to refer to humans as well as any other animals that are either male or female. They identify an individual's sex, which is an essential element of determining sex-based discrimination under Title IX. This final rule does not interfere with the medical judgment of any covered entity in treating gender dysphoria, but Title IX cannot be used to require covered entities to ignore or override the underlying distinctions of sex that Title IX itself is premised upon.

The Department thus does not believe that Title IX requires participants in covered entities to use a pronoun other than the one consistent with an individual's sex and does not believe it otherwise appropriate to dictate pronoun use or force covered entities to recognize a conception of sex or gender identity with which they disagree for medical, scientific, religious, and/or philosophical reasons. This final rule does not prevent covered entities from maintaining or adopting pronoun policies, or endorsing a variety of theories of gender identity, to the extent otherwise allowed by statutory and constitutional law. This rule also does not prevent State and local jurisdictions from imposing such policies to the extent allowed by statutory and constitutional law.

Comment: A commenter contended that the Department exceeded its authority by proposing to roll back protections for transgender individuals, noting that a 2012 letter from OCR stated that Section 1557 protections included gender identity.[183]

Response: Consistent with the position taken by the Executive Branch on Title IX since 2017, the Department has concluded that the position stated in the 2012 OCR letter reflected an incorrect understanding of Title IX, as incorporated into Section 1557. The Department indefinitely suspended the sub-regulatory guidance contained in the 2012 letter in light of the proposed changes to the rule. 84 FR 27872 n.175. Having considered the matters raised fully, the Department disavows the views expressed in the 2012 letter that concern the coverage of gender identity and sex discrimination under Section 1557. Similarly, the Department disavows the views expressed in a voluntary resolution agreement entered into with The Brooklyn Hospital Center in 2015 resolving allegations of gender identity discrimination under Section 1557.[184] To the extent that those views were integrated or incorporated into the 2016 Rule with respect to gender identity, they are rescinded in this final rule.

Comment: Many commenters asserted that the proposed rule removes legal protections for transgender individuals and would allow or encourage providers to deny basic healthcare to individuals who identify as transgender. Commenters pointed to what they said were instances of discrimination on the basis of the identity of the patient as a transgender individual, where providers allegedly used excessive precautions, avoided touching the patient, engaged in unnecessary physical roughness in pelvic examinations, made insensitive jokes, intentionally concealed information about options for different treatments, asked unnecessarily personal questions, referred to transgender patients by pronouns and terms of address based on their biological sex rather than their gender identity, and/or disclosed a patient's medical history without authorization. Others cited 15 closed cases handled by OCR of alleged discrimination against transgender individuals in which providers had refused sex-specific care or coverage on the basis of discrepancies between the individual's sex and stated gender identity.

Response: The Department believes that all people should be treated with dignity and respect, regardless of their characteristics including their gender identity, and they should be given every protection afforded by the Constitution and the laws passed by Congress. The Department is committed to fully and vigorously enforcing all of the nondiscrimination statutes entrusted to it by Congress. For reasons explained above, the term ''on the basis of . . . sex'' in Section 1557 does not encompass discrimination on the basis of gender identity. Unprofessional conduct such as inappropriate jokes or questions, excessive precautions, or concealment of treatment options, may be covered under State medical malpractice, tort, or battery laws.

Commenters' concern about denial of basic healthcare to transgender

[180] *See* OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center (requiring assignment of persons to shared patient rooms according to gender identity) (2015), sub-regulatory guidance contained therein since *abrogated,* as discussed above, *https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/vra.pdf.*

[181] 81 FR 31406.

[182] *See Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (''As other courts have recognized, '[b]y definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth. '. . . The Complaint alleges that the RCHSD staff discriminated against Kyler by continuously referring to him with female pronouns, despite knowing that he was a transgender boy and that it would cause him severe distress. . . . Accordingly, Ms. Prescott's claim on behalf of Kyler survives under [Section 1557 of] the ACA.'').

[183] *See* Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), *available at https://perma.cc/RB8V-ACZU.*

[184] *See* OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center.

individuals appears to be based largely on unsubstantiated hypothetical scenarios. Although some rare instances have been reported, they are not recent, and the Department is unaware of a significant number of cases where a transgender individual who has accurately identified his or her (biological) sex to a provider has nonetheless been denied relevant, non-transition-related healthcare on the basis of his or her gender identity. The Department is not aware of any providers claiming that they see a need for or wish to make broad, identity-based denials of care. To the contrary, many providers who specifically object to the 2016 Rule's mandates with respect to sex-reassignment treatments and/or elective abortion procedures explicitly affirmed in comments their commitment to treat all patients without regard to self-identification, inclusive of gender identity or sexual orientation. In the anecdotes of discrimination reported by commenters, what is often being alleged is poor care or insensitive treatment rather than outright denial of care, and is often lacking documentation. This lack of substantial evidence supports the Department's understanding, in contrast to the allegations of some commenters, that denial of basic healthcare on the basis of gender identity is not a widespread problem in the U.S. Moreover, to the extent that the 2016 Rule provided against denial of basic healthcare on the basis of gender identity, those provisions of the rule have been preliminarily enjoined since December 2016 and have since been vacated; any future mistreatment hypothesized by commenters would not, then, be the result of this final rule.

Additionally, several of the behaviors alleged by commenters would be unlawful even if Title IX and Section 1557 had never been enacted. Unnecessary roughness in a pelvic examination, or any other medical procedure or examination without a medical basis or appropriate informed consent, may be a case of battery or malpractice, which should be reported to local law enforcement and/or licensing authorities. If such conduct willfully causes bodily injury because of gender identity, and is in or affecting interstate commerce, then it could be a Federal hate crime.[185] When OCR becomes aware of any crimes that may violate Federal law, it may be required to make a referral to the Department of Justice.[186] The Emergency Medical Treatment and Labor Act (EMTALA) also requires stabilization in certain emergency medical situations.

OCR also continues to enforce Federal health information privacy laws to ensure the confidentiality of all individuals' protected medical information, including information concerning gender dysphoria diagnosis or treatment, sexual orientation, or HIV status.[187]

The Department, through its Offices of Minority Health, supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: Commenters alleged that removing the definitions of ''gender identity'' and ''on the basis of sex'' (which includes gender identity) from the rule would ''erase'' transgender individuals from the *Code of Federal Regulations.*

Response: The Department denies that removal of definitional terms in one regulation has the wide-ranging impact that commenters allege. Under this final rule, transgender individuals remain protected by the same civil rights laws as any other individual, and the Department will vigorously enforce their statutory and regulatory civil rights. This final rule also does not and cannot erase explicit statutory protections for individuals on the basis of gender identity, such as in hate crimes laws that bar violence committed on the basis of an individual's gender identity.[188]

iii. Termination of Pregnancy

Comment: Commenters reacted to the proposed rule's elimination of the 2016 Rule's language that had encompassed ''termination of pregnancy'' within the definition of ''on the basis of sex.'' Commenters stated that the Department's declining to take a position about the full scope of the meaning of ''termination of pregnancy'' in the 2019 NPRM was confusing, and that the point merited clarification. Some providers objected to the inclusion of ''termination of pregnancy'' under the 2016 Rule to the extent that it referred to elective abortions. Other providers interpreted ''termination of pregnancy'' to mean both elective abortion and natural termination of pregnancies. Others stated that all forms of termination of pregnancy should be encompassed in the prohibition on discrimination on the basis of sex.

Some commenters stated that removing the 2016 Rule's definition of ''on the basis of sex'' will allow discrimination against women based upon their abortion history. Commenters also identified a variety of other women's healthcare services related to pregnancy that may be implicated, including prenatal and postpartum services, tubal ligations, and birth control (both as a contraceptive and when used to treat other medical conditions). They also referred to infertility treatments including in vitro fertilization, and pointed to *Benitez* v. *North Coast Women's Care Medical Group, Inc.*[189] as a real-world example of discrimination in this regard. Commenters said that the proposed rule would or could permit discrimination against women through denial or restriction of access to treatments such as these, as well as treatments prior to, during, or after a miscarriage.

Response: Under this final rule, the Department will interpret Section 1557's prohibition on sex-based discrimination consistent with Title IX and its implementing regulations. This final rule ensures that the Department's Section 1557 regulations are implemented consistent with the abortion neutrality and statutory exemptions in Title IX. The regulations are subject to the text of the Title IX statute, so they cannot 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.'' 20 U.S.C. 1688. As explained below, this final rule also incorporates that statutory text explicitly into the Title IX regulations for the sake of clarity, to ensure those regulations are

[185] 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on ''actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability'').

[186] *See* 34 U.S.C. 41303 (''All departments and agencies within the Federal government . . . shall report details about crime within their respective jurisdiction to the Attorney General''); 28 U.S.C. 535(b) (''any information, allegation, or complaint received in a department or agency of the executive branch of government relating to violations of title 28 involving Government officers and employees shall be expeditiously reported to the Attorney General by the head of the department or agency'').

[187] *See* U.S. Department of Health and Human Services, ''Careless handling of HIV information jeopardizes patient's privacy, costs entity $387k'' (May 23, 2017), available at *https://www.hhs.gov/about/news/2017/05/23/careless-handling-hiv-information-costs-entity.html* (OCR enforcement under HIPAA); *see also* U.S. Department of Health and Human Services, ''HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination'' (Oct. 30, 2019), *https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html* (OCR enforcement under Section 504 and Section 1557).

[188] *See* 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on ''actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability'').

[189] *Benitez* v. *N. Coast Women's Care Med. Grp., Inc.,* 106 Cal. App. 4th 978 (Mar. 4, 2003).

implemented consistent with the statute.

The *Franciscan Alliance* court vacated the ''termination of pregnancy'' language in the 2016 Rule because it failed to incorporate the abortion-neutrality language from the Title IX statute.[190] The Court held that ''Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions,'' [191] and concluded that by failing to include these exemptions, the Department unlawfully ''expanded the 'ground prohibited under' Title IX that Section 1557 explicitly incorporated.'' [192]

The Department is committed to enforcing vigorously the prohibition on discrimination on the basis of sex, through its implementing regulations (which include provisions on termination of pregnancy), as interpreted consistent with the text of Title IX. OCR will fully enforce its statutory authorities concerning any discriminatory denial of access to women's health services, including those related to pregnancy. The Department, however, declines to speculate on particular hypotheticals related to termination of pregnancy, and will proceed based on the specific facts and circumstances of each case that may arise.

Comment: Some commenters stated that without the 2016 Rule, there would be serious and/or life-threatening results because hospitals would not provide abortion care on the basis of religious beliefs, referencing *ACLU* v. *Trinity Health Corporation,* 178 F. Supp. 3d 614 (E.D. Mich. 2016), and *Means* v. *U.S. Conference of Catholic Bishops,* No. 1:15–CV–353, 2015 WL 3970046 (W.D. Mich. 2015). Some alleged that the proposed rule does not comply with constitutional law regarding abortion or the applicable standard of scrutiny for sex discrimination and imposes undue burdens on women. Some stated that the proposed rule would hurt women's health by denying or encouraging denial of access to abortion.

Others submitted evidence challenging the idea that the termination of pregnancy provision, if retained (and not enjoined by a court), would materially increase abortion access for the average person. Specifically, they state that the overwhelming majority of abortions in America are performed at high-volume abortion clinics, and that there is no reason to suspect that retaining the 2016 Rule would lead to a significant increase in hospitals or other institutions willing to perform abortions when compared to abortion providers as a whole. According to commenters, this is in part because many hospitals and medical institutions that do not have a formal position objecting to abortion are free to engage in them now yet do not perform them or do so only to a limited extent.[193] Additionally, commenters said that the relative dearth of doctors willing to perform abortions at institutions appears largely to be a result of independent physician choices, not of the policies of institutions that object to abortions.

Some commenters were concerned that the 2016 Rule's provisions on termination of pregnancy devalue human life, both with respect to unborn children who lose their lives, and with respect to mothers, as many abortions are dangerous and lead to life-threatening complications for women. Other commenters stated that HHS has a compelling interest in defending the sanctity of innocent human life at all stages. Some institutional providers who object to abortion stated that they can and do treat women who have had miscarriages, even using techniques that are commonly used in abortion (such as dilation and curettage), so long as the procedure itself is not intended to and does not result in the taking of a human life.

Response: The Department appreciates all comments related to the highly controversial matter of abortion. The strong views that Americans hold on various sides of this question are an important policy reason supporting the Congressionally-enacted abortion-neutrality language in Federal statutes such as Title IX. Because Section 1557 expressly incorporated Title IX—therefore including the abortion-neutrality provision—the Department likewise incorporates that provision for purposes of the covered entities under Section 1557. This final rule also does not add any abortion-related conscience protections beyond those that Congress has set down in statute. Those statutes have not been held to be unconstitutional. The Department will vigorously enforce these and all other Federal civil rights statutes under its jurisdiction.

This final rule also does not abrogate other longstanding Federal laws that may apply to situations related to pregnancy, including EMTALA and the Pregnancy Nondiscrimination Act. The Department will read all applicable laws and exemptions harmoniously.[194] In addition, the termination of pregnancy provisions of the 2016 Rule have been enjoined since December 2016 and are now vacated. Finally, this rule does not change the legal ability of providers to offer abortions. The Department therefore disagrees with commenters who predict that the finalization of this rule will significantly reduce abortion access or cause resulting health consequences.

iv. Sexual Orientation

Comment: Some commenters stated that the 2016 Rule's § 92.209 should be removed because Title VII and Title IX do not include sexual orientation in their prohibition of sex discrimination. They used as an example the fact that the previous Administration treated sex, sexual orientation, and gender identity as different concepts in an executive order that prohibited discrimination on the basis of sex, sexual orientation, and gender identity in Federal hiring, contracting, and employment.[195] They added that Congress has rejected the sexual orientation and gender identity provisions in the Employment Non-Discrimination Act, the Equality Act, and the Student Non-Discrimination Act.

Others said that sexual orientation is a foundational trait of an individual and that cannot be separated and/or isolated from his or her being and that the proposed rule would enable discrimination based on sexual orientation. Other commenters cite a general fear of discrimination; abuse or neglect related to sexual orientation; a

[190] *Franciscan Alliance,* 227 F. Supp. 3d 660, 690–91 (N.D. Tex. 2016) (''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,* 414 F. Supp. 3d 928, 945, 947 (N.D. Tex. 2019) (adopting reasoning from preliminary injunction and vacating the portions of the rule it deemed unlawful).

[191] *Franciscan Alliance,* 227 F. Supp. 3d at 690–91.

[192] *Id.* (citing *Corley* v. *U.S.,* 556 U.S. 303, 314 (2009)).

[193] As one commenter wrote, ''A 2018 study in the journal *Contraception* found that only 7% of obstetrician-gynecologists in private practice had performed an abortion in 2013 or 2014. An older study published in 2011 in *Obstetrics and Gynecology* found that 97% of practicing obstetrician-gynecologists encountered patients seeking an abortion, though only 14% performed them. Finally, a 2014 study published in *Perspectives on Sexual and Reproductive Health* found that just 5% of abortions take place in hospitals or physicians' offices, demonstrating that the vast majority of abortions are not performed by healthcare providers at hospitals or physicians' offices.''

[194] *See* 42 U.S.C. 13955dd(c)(1)(ii) (EMTALA); Public Law 95–555, 92 Stat. 2076 (Oct. 31, 1978) (Pregnancy Nondiscrimination Act).

[195] Exec. Order No. 13672, 79 FR 42971–72 (July 21, 2014), *https://www.govinfo.gov/content/pkg/FR-2014-07-23/pdf/2014-17522.pdf.*

lack of inclusive services; social isolation; a sense of invisibility; lack of educated providers; and distrust of the healthcare system. They argue that these burdens lead to inadequate care, including preventive care, and require a Federal response. In support of these claims, commenters cited a survey stating that 8% of lesbian, gay, and bisexual respondents allege they have been refused care from a healthcare provider due to their sexual orientation.[196] Other commenters, however, cited a survey showing that 97% of responding faith-based medical professionals attest that they ''care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when [they] cannot validate their choices.'' [197] Thus, some commenters argue, the issue is not one of refusing to care for certain patients based on identity, but instead a matter of declining to participate in a discrete set of morally controversial procedures and treatments that are available elsewhere.

Others said that discrimination because of an individual's sexual orientation is plainly a species of sex stereotyping that is impermissible under Section 1557's sex discrimination prohibition and cite *Baldwin* v. *Foxx,* an EEOC decision,[198] in support of the idea that the final rule should cover sexual orientation.

Response: OCR may only enforce laws that Congress has enacted and the regulations that were promulgated pursuant to that statutory authority. The plain meaning of ''sex'' under Title IX encompasses neither sexual orientation nor gender identity. Concerning commenters' discussion of Congress's failure to add sexual orientation and gender identity to contexts encompassed by Title IX or Title VII, the Department is guided primarily by its understanding of the plain meaning of the statute.[199] This final rule does not change the status quo with respect to sexual orientation, because, as the Department stated in the 2019 NPRM preamble, sexual orientation was not explicitly included in the 2016 Rule text,[200] and the Department has concluded that it is a category separate from sex and does not fall within the ambit of discrimination ''on the basis of sex.''

The U.S. Attorney General and Solicitor General have persuasively argued that *Price Waterhouse* does not elevate sexual orientation to a protected category using a sex stereotyping theory under Title VII, just as it fails to make gender identity a protected category under Title IX.[201] Much as the reasonable distinctions on the basis of sex discussed above (in the subsection on gender identity) are not illegitimate sex stereotypes, so too, distinctions on the basis of sexual orientation do not as such constitute sex stereotyping. As an initial matter, distinctions on the basis of sexual orientation may be sex-neutral and apply equally to both sexes, which would mean that they do not burden anyone on the basis of sex. The Eleventh Circuit has recently rejected the application of *Price Waterhouse* to expand ''sex'' to include ''sexual orientation,'' citing an abundance of case law in support.[202] Additionally, as the Solicitor General has argued, distinctions made on the basis of sexual orientation are not necessarily based on stereotypes, as they may instead be based on ''moral or religious beliefs about sexual, marital, and familial relationships.'' [203] ''There is nothing irrational or improper'' in such beliefs.[204]

The Department notes that in *Baldwin* v. *Foxx,* the EEOC reversed its long-held position that sexual orientation discrimination was not protected under Title VII.[205] The United States government has since rejected the

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[196] *See* Shabab Ahmed Mirza and Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, *Center for American Progress* (January 18, 2018), *https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.*

[197] *See* Freedom2Care, ''Conscience in healthcare: 2019,'' *https://www.freedom2care.org/polling.*

[198] *Baldwin* v. *Foxx,* EEOC Appeal No. 0120133080, 2015 WL 4397641 (July 15, 2015).

[199] The Department agrees that Congressional inaction on this issue is supportive of the conclusion that Title IX does not encompass sexual orientation or gender identity, although it does not rely on this Congressional inaction in interpreting Title IX.

[200] 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.'').

[201] *See Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *26 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)) (''Title VII prohibits disparate treatment of men and women regardless of sexual orientation. Gay, lesbian, and bisexual employees, no less than straight employees, may invoke *Price Waterhouse* if they are subjected to gender-based stereotypes; a gay man who is fired for being too effeminate has just as strong a claim as a straight man who is fired for that reason.''). *See also Etsitty* v. *Utah Transit Authority,* 502 F.3d 1215, 1224–25 (10th Cir. 2007) (explaining that the legal issue ''is whether members of one sex are exposed to disadvantageous terms or conditions of employment to which members of the other sex are not exposed'').

[202] *Evans* v. *Georgia Reg'l Hosp.,* 850 F.3d 1248, 1256–57 (11th Cir. 2017) (''*Price Waterhouse* and *Oncale* are neither clearly on point nor contrary to *Blum* [v. *Gulf Oil Corp.,* 597 F.2d 936 (5th Cir. 1979) (''Discharge for homosexuality is not prohibited by Title VII. . . .'')]. These Supreme Court decisions do not squarely address whether sexual orientation discrimination is prohibited by Title VII.'') *Id.* at 1256–57 (''Finally, even though they disagree with the decisions, [the plaintiffs] acknowledge that other circuits have held that sexual orientation discrimination is not actionable under Title VII. *See, e.g., Higgins* v. *New Balance Athletic Shoe, Inc.,* 194 F.3d 252, 259 (1st Cir. 1999) (''Title VII does not proscribe harassment simply because of sexual orientation.''); *Simonton* v. *Runyon,* 232 F.3d 33, 36 (2d Cir. 2000) (''Simonton has alleged that he was discriminated against not because he was a man, but because of his sexual orientation. Such a claim remains non-cognizable under Title VII.''); *Bibby* v. *Phila. Coca Cola Bottling Co.,* 260 F.3d 257, 261 (3d Cir. 2001) (''Title VII does not prohibit discrimination based on sexual orientation.''); *Wrightson* v. *Pizza Hut of Am.,* 99 F.3d 138, 143 (4th Cir. 1996), *abrogated on other grounds by Oncale* v. *Sundowner Offshore Servs.,* 523 U.S. 75, 118 S. Ct. 998, 140 L.Ed.2d 201 (1998) (''Title VII does not afford a cause of action for discrimination based upon sexual orientation. . . .''); *Vickers* v. *Fairfield Med. Ctr.,* 453 F.3d 757, 762 (6th Cir. 2006) (''[S]exual orientation is not a prohibited basis for discriminatory acts under Title VII.''); *Hamner* v. *St. Vincent Hosp. & Health Care Ctr., Inc.,* 224 F.3d 701, 704 (7th Cir. 2000) (''[H]arassment based solely upon a person's sexual preference or orientation (and not on one's sex) is not an unlawful employment practice under Title VII.''); *Williamson* v. *A.G. Edwards & Sons, Inc.,* 876 F.2d 69, 70 (8th Cir. 1989) (''Title VII does not prohibit discrimination against homosexuals.''); *Rene* v. *MGM Grand Hotel, Inc.,* 305 F.3d 1061, 1063–64 (9th Cir. 2002) (''[A]n employee's sexual orientation is irrelevant for purposes of Title VII. It neither provides nor precludes a cause of action for sexual harassment. That the harasser is, or may be, motivated by hostility based on sexual orientation is similarly irrelevant, and neither provides nor precludes a cause of action.''); *Medina* v. *Income Support Div.,* 413 F.3d 1131, 1135 (10th Cir. 2005) (''Title VII's protections, however, do not extend to harassment due to a person's sexuality. . . . Congress has repeatedly rejected legislation that would have extended Title VII to cover sexual orientation.'') (internal quotations omitted). *Evans* and the EEOC question these decisions, in part, because of *Price Waterhouse* and *Oncale.* Whether those Supreme Court cases impact other circuit's decisions, many of which were decided after *Price Waterhouse* and *Oncale,* does not change our analysis that *Blum* is binding precedent that has not been overruled by a clearly contrary opinion of the Supreme Court or of this Court sitting *en banc.*'').

[203] *Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)).

[204] *See Tuan Anh Nguyen* v. *INS,* 533 U.S. 68. *See also Obergefell* v. *Hodges,* 135 S. Ct. 2585, 2602 (2015) (referring to opinions that are ''based on decent and honorable religious or philosophical premises'' and are therefore not ''disparaged here''); *See Masterpiece Cakeshop* v. *Colorado Civil Rights Comm'n,* 138 S. Ct. 1719, 1729 (2018) (''To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: by describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.'').

[205] *See e.g., Angle* v. *Veneman,* EEOC Decision No. 01A32644, 2004 WL 764265, at *2 (Apr. 5, 2004) (recognizing that the EEOC had ''consistently held that discrimination based on sexual orientation is not actionable under Title VII''), *Marucci* v. *Caldera,* EEOC Decision No. 01982644, 2000 WL 1637387, at *2–*3 (Oct. 27, 2000).

EEOC's novel position.[206] Given Congress's decision not to extend civil rights protections on the basis of sexual orientation in the field of health and human services, the Department believes that State and local governments are best equipped to balance the multiple competing considerations involved in what remain a contentious and fraught set of questions.

v. Scrutiny for Sex-Based Classifications (Repeal of § 92.101(b)(3)(iv) of the 2016 Rule)

The Department proposed to repeal 92.101(b)(3)(iv) of the 2016 Rule, which forbids covered entities from operating a health program or activity restricted to members of one sex unless they can ''demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.'' [207]

Comment: Commenters stated that the 2016 Rule's provisions would pose an unjustified burden on, and lead to excessive scrutiny of, entities operating single-sex facilities in healthcare, as well as entities or persons who would claim religious or abortion exemptions under Title IX.

Response: The Department agrees that the 2016 Rule placed an unjustified burden on sex-specific health programs and activities conducted by private entities. The ''exceedingly persuasive justification'' legal standard under Equal Protection jurisprudence sets a limit to *governmental* actions that discriminate on the basis of sex, such as the military draft.[208] This standard is foreign to Title IX jurisprudence.[209] The 2016 Rule cited no case law in support of its decision to import a significantly modified version of this standard from constitutional law into its interpretation of ''on the basis of sex'' as defined by Title IX.[210] The express statutory exemptions to Title IX's nondiscrimination provisions, such as for fraternities and sororities, do not require individual covered entities to provide an ''exceedingly persuasive justification'' before being able to benefit from the exemption. Title IX also does not require religious entities to provide such a justification to qualify for the religious exemption from Title IX nondiscrimination provisions. To require such a justification in the enforcement of Section 1557 would be to impose a significant burden on private entities that the statutory text does not contemplate. Government actors are routinely subjected to levels of judicial scrutiny that private parties (even private parties receiving Federal funds) are not, such as where constitutional provisions restrict government action, or where statutes allow civil rights actions against State actors. *See, e.g.,* 1st Am., U.S. Const.; 42 U.S.C. 1983; 42 U.S.C. 2000bb, *et seq.* It would be inappropriate to constrain medical professionals' best judgment by requiring them to meet the governmental burden of proof every time they seek to draw a reasonable distinction on the basis of sex in providing healthcare or separate programs or activities for the two sexes.[211] As stated above, such distinctions are not inherently discriminatory: It is not discriminating against men to exclude them from, for example, gynecological services, because men are not similarly situated to women for purposes of such services. Providers accordingly should not be required to present an ''exceedingly persuasive justification'' for providing gynecological services only to women. OCR will, however, evaluate, and respond appropriately to, any allegations that a covered entity's sex-specific health programs or activities have in fact discriminated unlawfully on the basis of sex, including sexual harassment.[212]

vi. Disparate Impact Under § 92.101(b)(3)(iii) of the 2016 Rule

The Department proposed to repeal 92.101(b)(iii) of the 2016 Rule, which prohibited selection of sites or facilities that have an effect of discriminating on the basis of sex.[213]

Comment: Some commenters opposed repealing language that affirmed a disparate impact theory under grounds of nondiscrimination encompassed by Section 1557, contending that the civil rights statutes cited in Section 1557 authorize disparate impact claims.

One commenter asserted that the very existence of Section 1557 indicates that the ACA intends to extend protections against disparate impact discrimination to private rights of action: Title VI already applied in the context of healthcare programs and activities, so Section 1557 would have been meaningless if it did not also allow for private rights of action for disparate impact discrimination. The same commenter also took issue with the proposed rule's elimination of monetary damages for disparate impact claims.

Response: Case law has indicated that certain civil rights statutes incorporated by Section 1557 do authorize disparate impact claims: Namely, claims with respect to discrimination on the basis of race, color, national origin, and disability.[214] Title IX, however, authorizes no such claims regarding discrimination on the basis of sex. Similarly, provisions relating to site or facility selection based on race, color, national origin, or disability are found in HHS's Title VI and Section 504 regulations, but are not found in HHS's Title IX regulations.[215] Insofar as the 2016 Rule added new grounds of prohibited discrimination not found in the statute, the Department believes it is necessary to revert to the underlying statutes and their implementing regulations. As a result, to the extent any of the underlying statutes authorize disparate impact claims, this final rule will recognize such claims by virtue of its reliance on the governing statutes, regulations, guidance and case law applicable to such claims, without needing to delineate the availability or lack of availability of all possible claims in this final rule. In reviewing all complaints that raise a disparate impact claim, the Department will consider the circumstances of each complaint and will independently apply each statute and underlying regulation, according to its text and any applicable court precedents, to the health context under Section 1557.[216]

Comment: Some commenters stated that that the proposed rule's removal of protections against disparate impact discrimination, especially concerning race, color, and national origin, will lead to more instances of discrimination and fewer means of recourse.

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[206] *See* Brief for United States, *Bostock* v. *Clayton Cty. Bd. of Commissioners,* No. 17–1618 (U.S. filed Aug. 23, 2019).

[207] 81 FR 31470.

[208] *See Rostker* v. *Goldberg,* 453 U.S. 57, 69–70 (1981).

[209] *See, e.g.,* the clear distinction at *Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1046–50 (7th Cir. 2017) (''Title IX Claim''), and 1050–54 (''Equal Protection Claim,'' encompassing the ''exceedingly persuasive justification'' test).

[210] *Cf.* 81 FR 31408–09.

[211] *See* 2016 Rule, 81 FR 31409 (''In all cases, . . . OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex.'').

[212] *See* U.S. Department of Health and Human Services, ''HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar'' (2019), *https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html.*

[213] 81 FR 31470.

[214] *See* 45 CFR 84.4(b)(4) (Title VI); 80.3(b)(2) (Section 504).

[215] *See* 45 CFR 80.3(b)(3) (Title VI); 84.4(b)(5) (Section 504).

[216] The Department responds to comments on private rights of action and damages below in the section on the enforcement mechanisms of the 2016 Rule.

Commenters cited data about health disparities in LGBT and female populations that they asserted were caused by discrimination on the basis of gender identity or termination of pregnancy, and stated that disparate impact analysis under the 2016 Rule is the appropriate way to address such discrimination. Another commenter questioned the persuasiveness of assessing the relative proportion of health disparities between racial, transgender, and/or female populations and other populations. The commenter stated that the available data did not provide conclusive evidence that the health disparities were caused by discriminatory conduct against LGBT persons and individuals seeking abortions, because correlations are not definite evidence of causation. The commenter contended that the proposed rule's approach causes ambiguity by blurring the distinctions between the two.

Response: As an initial matter, the Department wishes to reiterate that it will enforce Section 1557 in light of its regulations that already protect against disparate impact on the basis of race, color, or national origin. With respect to concerns regarding disparate impact on LGBT and abortion-seeking populations, the Department notes that this final rule conforms the Section 1557 Rule to HHS's Title IX regulations, under which the disparate impact standard does not apply. This conformity provides a clearer standard for covered entities, which are no longer required to have legally sufficient knowledge of the causes of statistically disproportionate health disparities on the basis of sex or gender identity.

vii. Insurance Coverage in § 92.207 of the 2016 Rule

The 2016 Rule prohibited insurers from ''hav[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition.'' [217] Its preamble explained that this encompasses a ''range of transition-related services'' to treat gender dysphoria that are ''not limited to surgical treatments and may include, but [are] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual,'' and that may be required even if not ''strictly identified as medically necessary or appropriate'' insofar as the entity covers other types of similarly ''elective'' procedures.[218]

[217] 81 FR 31472, 31435–36.

[218] *Id.*

Comment: Commenters indicated support for the 2016 Rule's insurance coverage requirements, claiming that the Rule has led to increased access to gender transition services for transgender patients, and that these services will be lost if the proposed rule is finalized. In comments, clinicians provided information about the specific procedures, services, or treatments they perform or offer with respect to gender identity. Among those who offer medical interventions under the category of ''gender transition,'' there was a consensus that such interventions included genital sex reassignment surgeries, cross-sex hormonal treatment, counseling, and often psychological or psychiatric support. Some clinicians stated that only patients with longstanding identification as the opposite sex and distress with their biological sex sought these services. Beyond these, some (but not all) clinicians indicated that gender transition procedures could also include surgery for feminization or masculinization of the entire body, which could include reduction, augmentation, removal, or transplant of tissue, skin, hair, or body fat, as well as ''social transition'' services such as voice training.[219]

Some commenters regard transition services (which they said may include counseling, hormone therapy, and/or a variety of possible surgical treatments) as the governing standard of care. They directed the Department to studies on the matter including those cited in the 2016 Rule preamble, and cited what they said is a consensus of major American medical associations [220] about sex-reassignment surgery, cross-sex hormones, and affirmation counseling. Commenters urged the Department to follow the 2016 Rule in relying on the standards promulgated by the World Professional Association for Transgender Health (WPATH).[221]

Commenters stated that, under the WPATH standards and other protocols, treatment for gender dysphoria may require transition-related care.[222] Commenters asserted specific benefits from transition-related care in treating gender dysphoria.[223] For example, commenters said that access to transition services leads to decreased health disparities, such as lower levels of depression and suicide attempts.[224]

With respect to adolescents, some commenters promoted approaches that affirm or encourage gender identity variation, including sex reassignment, citing data that they said showed it resulted in fewer mental health concerns.[225] Some medical professionals also stated in comments that hormone blockers are a safe and reversible way to delay puberty, noting

[219] Examples of procedures identified were rhinoplasty, blepharoplasty, septoplasty, rhytidoplasty, abdominoplasty, electrolysis, liposuction, jawline modifications, scalp advancement, cheek and chin contouring, fat transfer, pectoral implants, forehead or brow lifts, or breast, buttocks, breast, waist, or lip augmentation/reduction. *See* Whitman-Walker Health; Philadelphia Transgender Center. HHS–OCR–2019–0007–138335 (Whitman-Walker Health). *http://www.thetransgendercenter.com/index.php/femaletomale1/ftm-price-list.html; http://www.thetransgendercenter.com/index.php/maletofemale1/mtf-price-list.html.*

[220] Commenters cited Jason Rafferty, ''Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents,'' 142 *Pediatrics* no. 4 (Oct. 2018) (American Academy of Pediatrics policy statement), and noted that the American Medical Association, the American College of Physicians, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the Endocrine Society the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, among others, support transition-related treatments.

[221] *See* 81 FR 31429.

[222] Commenters cited, for example, Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,* 102 The Journal of Clinical Endocrinology & Metabolism 3869 (2017); Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H–185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), *http://www.imatyfa.org/assets/ama122.pdf;* and Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012); *http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf* (citing WPATH *Standards*); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), *http://www.apa.org/about/policy/transgender.aspx.*

[223] Commenters cited, for example, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals.* J Sexual Medicine (Jan. 17, 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services,* J. Affective Disorders (Feb. 2018); and Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature,* 28 Int'l Rev. Psychiatry 44 (2016).

[224] Commenters cited, for example, Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth,* 56 J. Am. Acad. Child Adoles. Pyschiatry 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities,* 137 Pediatrics (2016); and Stephen T. Russel et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behaviors Among Transgender Youth,* 64 J. Adolescent Health 503 (2018), *https://www.jahonline.org/article/S1054-139X(18)30085-5/fulltext.*

[225] Commenters cited Hill DB, Menvielle E, Sica KM, Johnson A. *An affirmative intervention for families with gender variant children: parental ratings of child mental health and gender.* J Sex Marital Ther. 36(1):6–23 (2010).

they have been used historically for children experiencing precocious puberty, or puberty at a younger age.

Other commenters disagreed as to whether sex reassignment treatments or surgeries, or gender-affirming therapies, are the proper care for gender dysphoria, or even whether they are ever medically indicated. Instead of surgery, hormones, or cross-sex affirmation counseling, some healthcare providers recommended watchful waiting, talk therapy that affirms a person's biological sex, or psychological or psychiatric treatment of comorbid conditions, as distinct from permanent surgical or hormonal interventions.[226] These providers explained that patients with gender dysphoria can work with a psychiatrist or counselor to better understand their feelings and emotions, and how the incongruence between their psychological identity and biological sex causes them distress. Some clinicians stated that reinforcing a patient's perception that there is something wrong with their body is damaging both to mental and physical health of transgender patients.

Some medical professionals discussed the long-term and irreversible physical effects of cross-sex hormones and puberty blockers, pointing to permanent deepening of voice, clitoromegaly, jaw enlargement, permanent sterility, and sexual dysfunction.[227] Doctors also commented that clinical data have not shown that such hormonal treatments improve the long-term psychological functioning of gender dysphoric persons. Clinicians stated that certain hormone treatments given to persons with gender dysphoria result in glucose and lipid metabolism disorders and cardiovascular conditions. Some clinicians were critical of the research supporting transition services, stating that it does not adequately assess such long-term health consequences and ignores a particularly vulnerable population of patients, namely the growing population of transitioned individuals who wish to transition back but are being ignored or impeded from receiving services affirming their biology.[228] They cited research indicating that patients did not need surgical or hormonal transition services when less drastic interventions would have been effective.[229] Clinicians stated that transition services were burdensome on these patients on several levels—financially, physically, and psychologically. Commenters concluded that repeal of the 2016 Rule would relieve the burden on these transgender individuals by letting providers decide, based on their assessment of individuals, what surgeries or treatments are appropriate according to their medical judgment and without coercive regulatory pressure.

Some medical providers raised concerns that prescription of sex-reassignment procedures and treatments had risked the health of young patients under their care due to lack of capacity at young ages to fully consent to treatments, difficulties with proper diagnosis during changes undergone in adolescence, and the negative impacts on bone mass and growth, emotional development, and sexual function.[230] Some clinicians stated that gender dysphoria is not an immutable mental health condition and, as such, the appropriate treatment is not physical and permanent. Some clinicians stated that current care for gender dysphoria includes accommodation counseling, the ''wait and see'' approach, and (where indicated) detransition therapy, because dysphoria, particularly in children, has a high rates of resolving without other interventions. They said that in their medical judgment, sex reassignment, cross-sex hormones, and affirming counseling are new and controversial treatments with known permanent and negative health consequences. Some medical clinicians criticized the WPATH standards [231] for coming to policy conclusions without adequate clinical evidence and recommending treatments that are still experimental.[232] Other commenters criticized the 2016 Rule for relying on the policy recommendations of an international advocacy group to

[226] Commenters cited sources including Monique Robles, ''Observations in a Gender Diversity Clinic,'' 44 Ethics & Medics 2 (Feb. 2019); and Devita Singh, Ph.D., ''A Follow-up Study of Boys with Gender Identity Disorder,'' Department of Human Development and Applied Psychology, Ontario Institute for Studies in Education, University of Toronto (2012).

[227] Commenters cited sources including Talal Alzahrani, M.D., et al., ''Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population,'' *Circulation: Cardiovascular Quality and Outcomes* 12:4 (Apr. 2019), *https://www.ncbi.nlm.nih.gov/pubmed/30950651;* and Darios Getahun, M.D., et al., Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons, *Annals of Internal Medicine* (July 10, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29987313.*

[228] Commenters cited, for example, Miroslav L. Djordjevic et al., Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery, 13 J. of Sexual Med., 1000, 1006 (2016).

[229] Commenters cited, for example, Joe Shute, ''Sex change regret: Gender reversal surgery is on the rise, so why aren't we talking about it?'' *The Telegraph* (Oct. 1, 2017), *https://www.telegraph.co.uk/health-fitness/body/gender-reversal-surgery-rise-arent-talking.*

[230] Commenters cited, for example, Lieke Josephina Jeanne Johanna Vrouenraets, M.Sc., *et al.,* ''Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,'' *Journal of Adolescent Health* (Jan. 12, 2015), *https://www.ncbi.nlm.nih.gov/pubmed/26119518;* and Guido Giovanardi, ''Buying time or arresting development? The dilemma of administering hormone blockers in trans children and adolescents,'' *Porto Biomedical Journal* (2017).

[231] *See* Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People 16 (7th ed. 2011), *https://www.wpath.org/publications/soc.*

[232] Clinicians stated that the WPATH Standards ignored research evidence in support of a ''wait and see'' approach that gender dysphoria during childhood has a desistance rate, without drastic surgical or medical intervention for sex-reassignment or affirmation for social transition. They cited studies including Singh, D., ''A Follow Up Study of Boys with Gender Identity Disorder,'' doctoral dissertation submitted at University of Toronto (2012); Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J., ''A follow-up study of girls with gender identity disorder,'' *Developmental Psychology* 44:1 (2008), 34–45; Wallien, M. S. C., & Cohen-Kettenis, P. T., ''Prediction of adult GID: A follow-up study of gender-dysphoric children,'' paper presented at the meeting of the World Professional Association of Transgender Health, Chicago, IL (2007); and Smith, Y.L., Van Goozen, S.H., & Cohen-Kettenis, P. T., ''Adolescents with gender identity disorder who were accepted or rejected for sex reassignment surgery: A prospective follow-up,'' *Journal of the American Academy of Child & Adolescent Psychiatry,* 40:4 (2001), 472–81.

interpret U.S. nondiscrimination laws and develop policy in the American healthcare sector. Other commenters disputed the conclusions of medical professional associations referenced above, stating that they had mischaracterized the medical data, and that life-altering transition interventions are not medically necessary, effective, or safe.[233]

Several commenters who expressed objections to the 2016 Rule clarified that they do not exclude patients from access to healthcare on the basis of the patient's gender identity, but rather objected to the rule requiring that they provide treatment that would be detrimental to the health and well-being of their patients. Part of their medical profession involves recommendations on which treatments will appropriately treat medical conditions to improve the health of their patients, and the choice not to provide transition surgery or abortion is part of those judgments. Some providers indicated that the options for treatment they recommend for patients with gender dysphoria are therapeutic and accommodative counseling to improve long-term health outcomes, particularly of young patients.

Other commenters said the Department should rely on the recent reviews of the clinical data on sex-reassignment surgery and cross-sex hormonal treatment by science and healthcare professionals at HHS and DOD.

Response: These comments further reinforce the Department's conclusion, discussed above in the section on gender identity, that there is no medical consensus to support one or another form of treatment for gender dysphoria. In the Department's current view, the 2016 Rule did not give sufficient evidence to justify, as a matter of policy, its prohibition on blanket exclusions of coverage for sex-reassignment procedures. The Department shares commenters' judgment that the 2016 Rule relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding—such as the fact-finding that CMS undertook in deciding to not issue a National Coverage Determination with respect to sex-reassignment surgeries (as discussed above) due to insufficient proof of medical necessity. In addition, commenters identify a lack of clarity in the 2016 Rule's mandate, because of the lack of medical consensus as to what is even encompassed within ''gender transition procedures'' (*e.g.,* whether they include facial reconstruction or hair transplants). All these are further reasons why, as a matter of policy, Federal civil rights law should not be used to override providers' medical judgments regarding treatments for gender dysphoria. But as stated above, even if it were appropriate policy, such an end could not be achieved through application of Section 1557 and Title IX. There is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex.

Comment: Some commenters state that the provisions in § 92.207(b)(3) through (5) of the 2016 Rule were confusing, overbroad, unclear, and inconsistent. Commenters stated that specificity in this area is necessary for efficient and transparent operation of the health insurance coverage to work for all involved. Commenters expressed concerns that the 2016 Rule did not address whether insurers are required to pay for all such surgeries, including without prior approval; approve them absent some standard of medical necessity; or approve them even over concerns of later malpractice lawsuits by the patient. A commenter reiterated his comments on the 2015 NPRM that the 2016 Rule's requirements related to gender transition were confusing for covered entities. The commenter said the regulatory requirement did not address which healthcare providers must provide these surgeries: *e.g.,* plastic surgeons, thoracic surgeons, general surgeons, or physicians whether or not they ordinarily perform major surgery. Others stated that although the 2016 Rule preamble characterized the categorical exclusion provision as a ''limited'' exception, the provisions on gender transition-related services were very broad and could include facial feminization or masculinization surgeries. Some commenters interpreted ''gender dysphoria'' as only affecting transgender individuals who seek sex re-assignment services, but other commenters cited clinical data indicating that men who had genital combat injuries and women who had removal of cancerous tissue in breasts and have received the diagnosis may also experience body dysmorphia.[234]

Other commenters stated that surgical sex reassignment (which may also include cross-sex hormonal treatment) may cost up to $22,025 on average for those covered by insurers. Still others said that the definition of ''gender dysphoria'' itself has changed rapidly and unpredictably over the years, leading to confusion, and point to its shifting conception as an experience of distress or a personal characteristic, to different and changing terms used for diagnosis of gender dysphoria in the DSM, and to the varied use of both clinical medical terms and sociological identity terms concerning the topic. The American Psychiatric Association justified the abandonment of the term ''gender identity disorder'' and its replacement with ''gender dysphoria'' in the Diagnostic and Statistical Manual of Mental Disorders to reduce stigmatization of the particular mental condition, but commenters noted that the DSM–5 made no changes to remove the classification of ''disorder'' for suicidal ideation, other body dysmorphias, or substance use disorder, which mental health advocates commented are also stigmatizing and may be comorbid with gender dysphoria.

Response: The Department agrees that the 2016 Rule made confusing and overbroad demands on covered entities, including insurance providers, and left unclear to what extent it was requiring providers to provide, or health insurance issuers to cover, treatments such as facial feminization, Adam's apple reduction, and hair transplants as part of ''health services related to gender transition.'' This final rule seeks to handle issues involving the exercise of legitimate medical judgment (including determinations relating to medical necessity and coverage decisions) with greater care, and to provide covered entities with greater clarity regarding their regulatory obligations.

Comment: Some commenters who identified as transgender patients opposed the proposed rule on the grounds that they had budgeted and planned with the expectation that there would be a limited or no cost for transition services due to the 2016 Rule, but they were surprised when they had an out-of-pocket cost not covered by their selected insurance company or plan. A much higher cost for these services resulted in the inability to receive or delay in receiving such services. They described surprise billing at multiple steps of the process, from reviewing health insurance coverage plans to waiting for reimbursements. These commenters stated that they anticipated and relied on OCR's 2016

[233] *See* Michelle Cretella, ''Gender Dysphoria in Children'' (November 2018) (American College of Pediatricians policy statement); *see also* James Cantor, ''American Academy of Pediatrics Policy and Trans- Kids: Fact-Checking,'' *Sexology* (Oct. 2018).

[234] Commenters cited M. Jocelyn Elders, et al., ''Medical Aspects of Transgender Military Service,'' Armed Forces and Society 41(2) (Mar. 2014): 199–220.

Rule as guaranteeing them insurance coverage because it is provided to other patients, and that this was their understanding of the Affordable Care Act and their civil rights protections. Other commenters contended that the 2016 Rule had caused the reduction of blanket exclusions for gender transition in health insurance coverage over the past three years.[235] Others stated that short-term limited duration insurance plans do not provide coverage of gender transition-related services, and therefore if transgender individuals are covered by such plans, they would not be able afford medically necessary services.

Response: With respect to coverage for gender transition services, the Department notes that this final rule makes no changes to what has been the status quo since December 2016, when the Department was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket exclusions for sex-reassignment coverage is therefore more likely to be attributable to health insurance issuer or plan sponsor choice. State-level legal requirements concerning gender identity coverage have also come into effect in recent years, such as State statutes, regulations, guidance,[236] and court orders [237]—this final rule does not affect those changes in any way. But to the extent that provisions in the 2016 Rule did pressure any insurers to cover services on the basis of gender identity that they previously had not covered, such provisions did so without statutory authority, which is why they were preliminarily enjoined and vacated.

As a policy matter, the Department recognizes that surprise billing is a serious problem, but that topic is not a subject of this rulemaking. As for short-term limited duration insurance, for reasons discussed below, it is generally not regulated under this final rule and so is generally not affected by the rule's nondiscrimination requirements in any case.

e. Discrimination on the Basis of Association, Repeal of § 92.209 of the 2016 Rule

The Department proposed to repeal § 92.209 of the 2016 Rule, which included a prohibition on discrimination against an individual or entity on the basis of being known to or believed to have a relationship or association.

Comment: Commenters opposed the repeal of prohibitions against discrimination based on association with a protected category. These commenters contended that removing such protections would cause confusion, both for covered entities who will be unsure of their responsibilities and for individuals who will be unsure of their rights, especially in light of other Federal nondiscrimination laws that the Department enforces. For example, the Department enforces Title II of the ADA and its implementing regulation, which prohibits discrimination against an individual based on his or her association with another individual with a disability, as do Titles I and III of the ADA.[238] Commenters said that this also shows that it would defy Congressional intent, and cause inconsistency among different regulations that covered entities are subject to, if the Department were to withdraw associational discrimination protections from patients seeking healthcare. Commenters also expressed concern that the proposed rule would make it more difficult for those experiencing discrimination by association to enforce their rights. Other commenters stated that the lack of reference to associational discrimination in the proposed rule is inconsistent with existing case law that validates prohibitions on associational discrimination, particularly in employment discrimination cases brought under Title VII pertaining to race, sex, and religion. Others argued that it is incorrect to assume that by referencing the grounds protected under previous civil rights laws, Section 1557 automatically incorporates the limitations found in those laws.

Some commenters contended that specific protected populations are more susceptible to associational discrimination. In particular, commenters stated that deaf and hard-of-hearing patients frequently use hearing companions, especially in hospital settings, and may be subject to associational discrimination. Commenters also identified potential instances of associational discrimination, including an entity's refusing to provide medical services to a white individual due to association with an African American individual, refusing to provide medical services to a child because his parents speak a different language, or refusing to provide services to an individual because her family members have a specific disability.

Response: This final rule neither abrogates nor withdraws any protections available under the incorporated civil rights statutes or their implementing regulations. It simply declines to use the Section 1557 regulation to identify protections beyond those specifically identified in the text of the relevant statutes and regulations. Protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under those statutes and regulations. As stated above, the Department regards this as the best way to decrease confusion. As the *Franciscan Alliance* court noted, the executive branch is obligated to implement Section 1557, with the civil rights statutes it incorporates, by ''giving the statutory text its plain and ordinary meaning, construing the statute as a whole, and giving effect to every word of the statute.'' [239] Courts have held that Section 1557 incorporates the limitations of the civil rights statutes referenced in Section 1557.[240]

Some instances discussed by commenters would appear to constitute discrimination against a person under the underlying civil rights statutes even without the 2016 Rule's prohibition on associational discrimination. For example, if a covered entity refused to provide meaningful access for LEP parents who are legally entitled to make medical decisions on behalf of their child, it could constitute discrimination on the basis of national origin.

f. Multiple Protected Statuses

The Department received many comments about individuals who may have protected status or face discrimination on multiple grounds.

[235] Commenters cited sources including, *e.g.,* Out2Enroll, Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557 (finding that 18.5% of insurers in 2017, 28% of insurers in 2018, and 94% of the insurers did not include blanket exclusions in their plans).

[236] *See, e.g.,* Calif. Health and Safety Code 1365.5; Colo. Insurance Bulletin No. B–3.49; Conn. Insurance Bulletin IC–34; 79 Del. Laws Ch. 47; DC Code 31–2231.11; Haw. Rev. Stat. 431:10A–118.3, 432:1–607.3, 432D–26.3; 50 Ill. Adm. Code 2603.35; Mass. Insurance Bulletin 2014–03; Nev. Rev. Stat. 651.070; Nev. Admin. Code 686A.140(7); 11 New York Codes Rules and Regulations 52.16; New York Insurance Code 2607, 3243, 4330; Ore. Rev. Stat. 746.015; Ore. Admin. Rules 836–080–0055; 46 Pa. Bulletin 2251; Rhode Island Health Insurance Bulletin 2015–3; 8 Va. Stat. Ann. 4724; Vt. Insurance Bulletin 174; Wash. Rev. Code 48.30.300.

[237] *See, e.g., Outfront* v. *Piper,* No. 62–cv–15–7501 (Minn. D. Ct. Nov. 14, 2016) (interpreting the state Constitution as applied to MinnesotaCare); *Good* v. *Iowa Dept. of Human Services,* No. 18–1158 (Iowa S. Ct. Mar. 8, 2019) (interpreting the Iowa Civil Rights Act as applied medical assistance).

[238] 28 CFR 35.130(g) (Title II); 42 U.S.C. 12112(b)(4) (Title I); 42 U.S.C. 12182(b)(1)(E) (Title III).

[239] *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016).

[240] *See, e.g., Condry* v. *UnitedHealth Group,* 2018 WL 3203046 (N.D. Cal. Jun 27, 2018) (''disparate impact claims on the basis of sex are not cognizable under section 1557'').

Comment: One commenter stated that because the 2016 Rule covers discrimination based on multiple protected statuses, the proposed rule would create a confusing mix of legal standards and available remedies and therefore could limit claims of intentional discrimination, while the 2016 Rule makes it easier for members of the public to file complaints of intersectional discrimination in one place.

Response: OCR has long accepted complaints alleging discrimination based on more than one protected status. OCR has handled those complaints, and will continue to handle them, under the implementing regulations of each of its applicable civil rights laws. Nothing in this final rule changes that. OCR's complaint form provides the public with the option to select multiple forms of prohibited discriminatory practices, such as both race and disability. OCR continues to encourage the public to file complaints about potentially unlawful discrimination, whether on one prohibited basis or on multiple prohibited bases.

Comment: Commenters stated that the proposed rule would compound discrimination faced by individuals with multiple protected characteristics, such as people of color who are also LEP or disabled. Some commenters said that African Americans are more likely to live with disabilities and chronic conditions, and thus would be disproportionately affected by relaxing discrimination restrictions for health insurance plans.

Response: The Department commits itself, in this final rule, to fully enforce Section 1557 according to its text and the text of the underlying statutes, as well as under the Department's implementing regulations for those statutes, as applied to the health context. Although the Department is proposing to repeal the nondiscrimination provision of the 2016 Rule at § 92.101, this final rule replaces it with a general provisions section at § 92.2. The new section will maintain the nondiscrimination requirements required by Title VI, Title IX, the Age Act, and Section 504. As such, individuals with multiple protected characteristics, such as race and disability, would be protected under the Department's enforcement of Section 1557 to the extent those statutes and regulations apply. Those statutes and regulations explain which characteristics are protected.

With respect to LEP and disability, this final rule additionally contains specific sections clarifying those protections. The underlying regulations and guidance for enforcing these statutes establish standards that are well-known by covered entities. The Department will continue to robustly enforce these statutes, and believes this final rule provides appropriate language to ensure that enforcement occurs.

Comment: Commenters contend that African American, Asian American and Pacific Islander, and Native American women are more likely to die from pregnancy-related complications and will be disproportionately affected by changes to the interpretation of sex discrimination in the proposed rule. Others contend that LGBT people of color will be harmed by the proposed regulation; they also state that LGBT people of specific national origins, including Native American and Middle Eastern, experience high rates of negative experiences in healthcare settings related to gender identity. Commenters alleged the proposed rule would disproportionately harm Native American women, women of color, and transgender individuals who are minorities.

Response: As discussed above, the 2016 Rule's definition of ''on the basis of sex'' is not included in this final rule because it exceeded the Department's statutory authority. In addition, with respect to gender identity and termination of pregnancy, the court's longstanding preliminary injunction and eventual *vacatur* of that language means that the results some commenters fear from removing such language would not be the result of this final rule. The Department is not aware of data supporting commenters' assertion that this change will have a disparate impact on the basis of race or national origin, although even if it did, that disparate impact would be attributable to the statutes rather than to this final rule. To the extent that the Department learns that individuals suffer barriers to healthcare on the basis of race, national origin, or any other protected characteristic, it will work to address those barriers within the limits of its statutory authority.

g. Examples of Discriminatory Practices (Repeal of § 92.207 of the 2016 Rule)

The Department proposed to repeal § 92.207 of the 2016 Rule, which stipulated that covered entities must not discriminate on the prohibited bases in providing or administering health-related insurance or other health-related coverage, and listed examples of such prohibited discrimination. Comments pertaining to § 92.207(b)(3)–(5) related to gender identity are discussed above in the section on discrimination on the basis of sex.

Comment: Commenters opposed repealing the explicit provisions of § 92.207 that prohibit covered entities from discriminating in health insurance or other health coverage. Commenters argued that the proposed rule did not provide any reasoned legal or policy basis for the repeal, which precluded the opportunity to provide public comment on the Department's justifications and so violated the APA. While the proposed rule discussed repealing provisions that may be duplicative, inconsistent, or confusing, commenters argued that the Department did not explain under which of these grounds it was repealing § 92.207, and that the proposed rule's supporting footnote [241] listed comparator regulatory citations that did not duplicate or contradict the provisions of § 92.207.

Commenters also expressed concern that repealing this section would allow health insurance issuers to discriminate, particularly with regard to benefit design, and could make it harder for people who experience discrimination to enforce their rights through administrative and judicial complaints. Commenters asserted that, prior to the ACA, health insurance issuers avoided covering costly individuals by employing the discriminatory practices prohibited by § 92.207, and that repealing these explicit prohibitions would allow health insurance issuers to again discriminate in a variety of ways, including by excluding or denying benefits, applying age limits, increasing costs for sicker enrollees, imposing utilization management limitations, and designing discriminatory prescription drug formularies. Commenters also argued that the ACA was intended to increase administrative oversight of private health insurance plans and to prevent discrimination in health insurance, particularly in light of the underlying civil rights laws' historically limited application to private health insurance and benefit design prior to the ACA.

Several commenters argued that the removal of specific nondiscrimination provisions under § 92.207 would make the regulation vague, eliminate guidance for covered entities, and create confusion about what is prohibited conduct, thereby increasing legal

[241] 84 FR at 27869 n.147 (comparing 45 CFR 92.207 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).'').

uncertainty and risk. This argument was reiterated by some State government regulators, who said that the specificity in the law provides clarity for both covered entities and the State, with State regulators often relying upon the standards in the 2016 Rule to ensure nondiscrimination in health insurance. Other commenters said that the repeal of § 92.207, compounded with the repeal of language access and taglines requirements, would open the door to discrimination based on national origin by healthcare providers.

Response: The number, breadth, and depth of comments received and discussed in this preamble indicate that the public was given an adequate opportunity to provide comment on the Department's justifications for this final rule.

Commenters are correct to note that the ACA has significantly expanded the applicability of Federal civil rights laws to private health insurance plans. That is why, under this final rule, all health insurance programs that remain covered by Section 1557 remain prohibited from discriminating on the grounds specified by the statute. This final rule has a section on scope at § 92.3, and the Department does not believe the rule needs an additional or separate section on health insurance in order to make this clear. OCR will examine carefully any allegations of discrimination by health insurance issuers, including through benefit design, and will vigorously enforce Section 1557's prohibitions. The Department also notes that certain health insurance issuers remain subject to similar nondiscrimination requirements under statutory provisions implemented and the regulations issued by CMS's Center for Consumer Information and Insurance Oversight (CCIIO). Commenters' specific concerns about national origin discrimination are addressed above and below in the relevant sections.

The 2019 NPRM listed § 92.207 among passages of the 2016 Rule that ''are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations.'' [242] As the footnote referenced by commenters shows, the Department specifically pointed there to preexisting HHS regulations under those statutes regarding health benefits and health insurance.[243] The substantive overlap between these regulations and § 92.207 is sufficient to show that the latter either duplicates them, or is inconsistent with them, or may be confusing as to whether it is duplicating them or contradicting them. Because Section 1557 does not require a regulation, the Department prefers to enforce the relevant statutes, to the extent possible, through their existing regulations. The changes in the 1557 regulation made by this final rule advance the Administration's goal of reducing the regulatory burden of the ACA and of administrative action in general.[244]

The 2016 Rule's list of examples of prohibited conduct by insurers at § 92.207(b) was followed by a catchall provision at § 92.207(c) stipulating that the enumeration of those specific forms of discrimination was no limitation on the general prohibition on insurers' discriminating on the prohibited grounds. That catchall provision made § 92.207 no less vague, and gave it no less potential to cause confusion, than this final rule's general prohibition on discrimination by covered entities. The Department declines in this preamble to give guidance of this kind to State regulators, who must each work within their own State's regulatory framework for health insurance. The Department notes that State regulators may also rely upon regulations issued by CCIIO, as applicable.

h. Summary of Regulatory Changes

For the reasons discussed herein, and considering the comments received, the Department finalizes its proposed new § 92.2 without change, its repeal of § 92.4 without change, its repeal of the notice requirement in § 92.8(d) and Appendix B without change, and its repeal of § 92.101, 92.206–92.207, and 92.209 without change.

(5) Assurances in Proposed § 92.4, and Repeal of § 92.5 of the 2016 Rule

The Department proposed that the 2016 Rule's provision at § 92.3 requiring an assurance of compliance with Section 1557 be retained and redesignated § 92.4. 84 FR at 27863. Here, as throughout the proposed rule, the Department also updated the 2016 Rule's term ''State-based Marketplace℠'' to read ''State Exchange,'' in conformity with current CMS regulations. 84 FR at 27871.

Comment: Comments contended it is unclear whether submitting assurances required under this provision at § 92.4 would also fulfill the assurance requirements of Section 504 at 45 CFR 84.5.

Response: As under the 2016 Rule, the application package for all HHS grant-making agencies continues to include a requirement that the applying entity submit a signed assurance form (Form 690), which specifically references Section 1557 along with Title VI, Title IX, Section 504, and the Age Act. That form is available at *https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf.* All recipients of Federal financial assistance from HHS are required to submit the consolidated form that satisfies the assurance requirements for both Section 1557 and these four other civil rights statutes.

The Department requested comment on whether this proposal struck the proper balance by retaining the assurance provisions from the 2016 Rule, and whether the benefits of these provisions exceed the burdens imposed by them.

Comment: Some commenters expressed their support for maintaining the current assurance of compliance requirement, noting that an assurance of compliance is an important step towards ensuring that covered entities know their obligations under Section 1557 and remain compliant. Additionally, questions were raised regarding which entity would be responsible for oversight, enforcement, and corrective action should a covered entity violate Section 1557 despite assuring its compliance.

Response: OCR is responsible for enforcing Section 1557 and will provide oversight, enforcement, and corrective action should a covered entity violate its obligations under Section 1557. The Department agrees that assurances of compliance provide valuable services by alerting covered entities of their obligations, and will retain these provisions under § 92.4 of this final rule.

Summary of Regulatory Changes: For the reasons given in the proposed rule, and having considered comments received, the Department finalizes its proposed § 92.4, and repeal of § 92.5 of the 2016 Rule, without change.

(6) Enforcement Mechanisms in Proposed § 92.5, and Repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule

The Department proposed provisions on enforcement of Section 1557 at the new § 92.5, 84 FR at 27863, and proposed to repeal §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and

[242] 84 FR 27869.

[243] *See* 84 FR at 27869 n.147.

[244] Executive Order 13765 on Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 FR 8351 (Jan. 20, 2017); Executive Order 13771 on Reducing Regulation and Controlling Costs (Jan. 30, 2017); Executive Order 13777 on Enforcing the Regulatory Reform Agenda (Feb. 24, 2017); Executive Order 12866 on Regulatory Planning and Review, 58 FR 190 (Oct. 4, 1993), at § 1(b)(10).

Appendices A and C of the 2016 Rule, which also provided for enforcement mechanisms and notices.

a. Enforcement Procedures and Underlying Regulations in § 92.5(a) (Repeal of § 92.302 and § 92.6(a) of the 2016 Rule)

Proposed § 92.5(a) applies 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, with their respective implementing regulations, to Section 1557.

Comment: Various commenters expressed opposition to the Department's proposal to replace § 92.301 with § 92.5, and requested that the Department retain § 92.301. Others expressed the view that by adopting § 92.5, the Department would be incorrectly limiting the remedies available under Section 1557. Several commenters asserted that enforcement would be more difficult under the proposed rule because, they said, it creates a patchwork of legal standards—unlike the 2016 Rule, which used a single standard that permitted disparate impact claims. They said this would create confusion, hamper enforcement, and dilute the protections provided to individuals.

Response: This final rule properly limits the remedies available under Section 1557. The text of the 2016 Rule, at § 92.301(a), stated that the enforcement mechanisms available and provided for under Title VI, Title IX, Section 504 and the Age Act shall apply for the purposes of Section 1557.[245] But upon reconsideration of these issues, the Department concludes the 2016 Rule applied these mechanisms in a confusing and inconsistent manner. For certain covered entities, it applied Title VI mechanisms, not only to grounds of discrimination prohibited under Title VI, but also to those prohibited under Title IX and Section 504, while leaving Age Act mechanisms in place for the grounds of discrimination it prohibits; for other covered entities, it applied Section 504 mechanisms, not only to grounds of discrimination prohibited under Section 504, but also to those prohibited under Title VI, Title IX, and the Age Act.[246] The 2016 Rule's regulatory structure blended new standards and preexisting standards from underlying civil rights regulations, and imposed those standards alongside the underlying regulations, which were left in place. In contrast, this final rule adopts the enforcement mechanisms for these four statutes and their implementing regulations *respectively,* each for its own statute. The Department believes this minimizes the patchwork effect of the 2016 Rule by using a familiar regulatory regime under those four statutes. The Department also believes this approach is what the statutory text contemplates. Moreover, because OCR has significant experience enforcing civil rights claims using these civil rights statutes' regulations, the Department expects this change to improve enforcement of Section 1557 and, by removing possible confusion, to make it easier for both individuals and covered entities to know their rights and responsibilities.

Comment: One commenter said that the Department's proposal to remove the 2016 Rule's single standard for enforcing claims is inconsistent with the Minnesota District Court's finding in *Rumble* v. *Fairview Health Services* that ''Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status.'' [247]

Response: The Department disagrees with this commenter's suggestion that it is inappropriate to finalize the proposed rule's repeal of provisions containing certain enforcement mechanisms. The Minnesota District Court found the language of the Section 1557 statute to be ''ambiguous, insofar as each of the four statutes utilize[s] different standards for determining liability, causation, and a plaintiff's burden of proof,'' [248] and concluded that the Department's interpretation of Section 1557 was permissible. However, the Minnesota District Court view is the minority view and has subsequently been rejected by multiple other court rulings that postdate the 2016 Rule.[249] The Department agrees with these latter courts' reasoning. To the extent that the statutory language could be ambiguous, as the Minnesota district court concluded, the Department believes that its new interpretation is a better and reasonable interpretation of the statute, and is at least an equally permissible statutory interpretation, and therefore is entitled to *Chevron* deference, *Chevron U.S.A., Inc.* v. *NRDC,* 467 U.S. 837 (1984). That the Department's interpretation represents a break with a previous interpretation does not preclude the Department from reinterpreting the statute and receiving *Chevron* deference for its new interpretation, *see, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 186–87 (1991). Here, the Department believes that this final rule's approach is the one best suited to reducing confusion and robustly enforcing Section 1557's nondiscrimination provisions.

b. Compensatory Damages (Repeal of § 92.301(b) of the 2016 Rule)

The Department proposed to repeal § 92.301(b) of the 2016 Rule, which provided for compensatory damages for any and all claims under Section 1557.

Comment: Some commenters opposed the changes to the enforcement mechanisms under the proposed rule and asserted that Section 1557 makes available to all individuals any of the enforcement mechanisms available under any of the four civil rights statutes, including but not limited to compensatory damages.

Response: Although the 2016 Rule stated that compensatory damages are available in appropriate administrative and judicial actions under the Section 1557 regulation, the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual. 84 FR at 27851. The manual states that, under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations.[250] Consequently, the Department considers it most appropriate to finalize this rule by eliminating § 92.301(b) and reverting to enforcement under the regulations applicable to Title VI, Title IX, the Age Act, or Section 504. To the extent compensatory damages are, or are not,

[245] 81 FR 31472.

[246] *Id.*

[247] 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015).

[248] *Id.* at *10.

[249] *See Briscoe* v. *Health Care Svc. Corp.,* 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) (''Taken together, the first two sentences of § 1557 unambiguously demonstrate Congress's intent 'to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.'''), quoting *Southeastern Pennsylvania Transp. Auth.* v. *Gilead Sciences Inc.,* 698–99 (E.D. Pa. 2015); *York* v. *Wellmark, Inc.,* 2017 WL 11261026, at *18 (S.D. Iowa Sept. 6, 2017) (''Congress clearly intended to incorporate the statutes' specific enforcement mechanisms rather than create a general catch-all standard applicable to all discrimination claims.''). *See also Galuten on Behalf of Estate of Galuten* v. *Williamson Med. Ctr.,* 2019 WL 1546940, at *5. (M.D. Tenn. Apr. 9, 2019) (same); *E.S. by and through R.S.* v. *Regence BlueShield,* 2018 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *Doe* v. *BlueCross BlueShield of Tennessee, Inc.,* 2018 WL 3625012, at *6 (W.D. Tenn. July 30, 2018).

[250] *See* 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)).

available under those regulations, the regulations will provide for enforcement of Section 1557 in applicable circumstances in the same way.

This approach is consistent with both the best interpretation of the text and the court decisions (cited above) indicating that Section 1557 does not impose a single standard but instead incorporates the distinct enforcement mechanisms of each of the four civil rights statutes described in Section 1557.[251]

c. Implied Private Rights of Action (Repeal of § 92.302(d) of the 2016 Rule)

The Department proposed to repeal § 92.302(d) of the 2016 Rule, which stated that an individual or entity may bring a civil action in a United States District Court to challenge a violation of Section 1557 or the 2016 Rule.

Comment: Some commenters opposed repeal of this language. Several commenters argued that the existence of a private right of action is clear from the statutory language in Section 1557, which they say explicitly references and incorporates the enforcement mechanisms of the four civil rights laws listed, including a private right of action. They cited cases that allow for Section 1557 to include enforcement mechanisms separate from the mechanisms in underlying statutes.[252] Commenters said that the creation of a private right of action within Section 1557 is consistent with Congress's intent that civil rights laws be broadly interpreted to effectuate the remedial purposes of those laws, and that removing Section 1557's private right of action is inconsistent with precedent of the United States Supreme Court, which has upheld private rights of action under the preexisting civil rights laws.

Response: Upon reconsideration of this issue, the Department no longer intends to take a position in its regulations on the issue of whether Section 1557 provides a private right of action. To the extent that Section 1557 permits private rights of action, plaintiffs can assert claims under Section 1557 itself rather than under the Department's Section 1557 regulation.

Comment: Commenters requested that the Department adopt a regulatory framework for Section 1557 where there is a requirement for exhaustion of administrative remedies before a party can bring a private right of action.

Response: Because the Department is eliminating the language specifying a right to sue, the Department does not consider it necessary to establish a framework and a requirement for exhaustion of administrative remedies before filing suit in court.

d. Voluntary Action (Repeal of § 92.302(c) and § 92.6(b) of the 2016 Rule)

The Department proposed to repeal § 92.302(c) of the 2016 Rule, as well as § 92.6(b), which set forth provisions concerning voluntary cooperation with requests for information, and voluntary action beyond the requirements of Section 1557. These provisions have parallels in the regulations implementing Title VI, Section 504, Title IX, and the Age Act,[253] which the Department will use to enforce Section 1557.

The Department did not receive comments specific to these sections.

e. Access to Records of Compliance (Repeal of § 92.303(c) of the 2016 Rule)

The Department proposed to repeal § 92.303(c) of the 2016 Rule, which set forth the Department's obligations to permit access by OCR to review records and sources of information, and to otherwise comply with OCR investigations under the 2016 Rule.

Comment: Commenters expressed concern that the proposed rule undermines the Department's enforcement authority concerning compliance with Section 1557 by programs and activities administered by the Department.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions addressing access to review of covered entities' records of compliance.[254] The language in the 2016 Rule to this effect was unnecessary, as OCR has the tools to review records and sources of information under existing regulations.

f. Prohibitions on Intimidation and Retaliation (Repeal of § 92.303(d) of the 2016 Rule)

The Department proposed to repeal § 92.303(d) of the 2016 Rule, which concerns intimidation and retaliation provisions that pertain to the Department.

Comment: Several commenters contended that under the proposed rule, those bringing Section 1557 claims would no longer be explicitly protected from retaliation and discrimination.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions against intimidation and retaliation as appropriate.[255] The language in the 2016 Rule to this effect was unnecessary. Moreover, OCR ensures the confidentiality of complainants under all the statutes it enforces, to the extent permitted by law and consistent with OCR's investigative needs. In some cases, the Freedom of Information Act, the APA, or other laws may require disclosure of certain information provided by complainants.

g. Perpetuating Discrimination by Assistance and Utilizing Criteria or Methods of Administration (Repeal of § 92.101(b)(1)(ii), (b)(3)(ii), and (b)(4)(ii) of the 2016 Rule)

The Department proposed to repeal § 92.101(b)(1)(ii) and § 92.101(b)(4)(ii), which prohibited significant assistance to any agency, organization, or person that discriminates on the basis of race, color, national origin, or age. The Department also proposed to repeal § 92.101(b)(3)(ii), which prohibited utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex.

Comment: One commenter objected to repealing the prohibition on the utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex. Arguing that Section 1557 is its own authority, the commenter stated that it is irrelevant that the Title IX regulations do not

[251] *See Galuten,* 2019 WL 1546940, at *5 n.8 (because ''the Age Discrimination Act would not authorize [ ] compensatory damages,'' ''it appears that a Federal court with jurisdiction would be constrained to dismiss Plaintiff's claims for compensatory . . . damages under the ACA'').

[252] Commenters cited *Edmo* v. *Idaho Dep't of Corr.,* No. 1:17–cv–00151–BLW, 2018 WL 2745898, at *9 (D. Idaho June 7, 2018) (''[C]ross-referencing the statutes and the express incorporation of the enforcement mechanisms from those statutes is probative of Congressional intent to provide both a private right and a private remedy for violations of Section 1557.''); *Esparza* v. *Univ. Med. Ctr. Mgmt. Corp.,* No. 17–4803, 2017 WL 4791185, at *5 (E.D. La. Oct. 24, 2017) (concluding it was ''abundantly clear to the Court that Congress intended to create a private right of action to enforce § 1557''); *Doe One* v. *CVS Pharmacy, Inc.,* 348 F. Supp. 3d 967, 982 (N.D. Cal. 2018) (finding plaintiffs had not sufficiently alleged disparate impact); *see also Cannon* v. *Univ. of Chi.,* 441 U.S. 677, 703 (1979) (recognizing that Congress intended to create Title IX remedies comparable to those available under Title VI, including a private cause of action for victims of the prohibited discrimination, and finding that age and advanced degrees criteria had a disparate impact on women); *Rumble* v. *Fairview Health Servs.,* 2015 WL 1197415.

[253] *See* 45 CFR 80.7(d), § 80.8(c)(1) (Title VI); § 84.6(b) (Section 504); proposed § 86.71 (Title IX incorporating 45 CFR 80.7(d)); § 90.49(c) (Age).

[254] *See* 45 CFR 90.45, § 91.31 (Age Act) and § 80.6(c) (Title VI); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.6(c)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.6(c)).

[255] *See* 45 CFR 80.7(e) (Title VI); § 91.45 (Age Act); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.7(e)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.7(e)).

contain a disparate impact provision. Some commenters also contended that removing the ''significant assistance'' provision would undermine enforcement.

Response: The prohibition on perpetuating discrimination by providing significant assistance to any agency, organization, or person that discriminates is identified only in the Title IX and Section 504 regulations, as applied to sex and disability discrimination claims; [256] the 2016 Rule applied it also to claims on the basis of race, color, national origin, or age. Similarly, as discussed above in the section on discrimination on the basis of sex, there is no disparate impact language in the Department's Title IX regulations, but the 2016 Rule made such language applicable to sex discrimination claims brought under Section 1557. For the reasons given earlier in this section, the Department considers it appropriate to rely on the enforcement mechanisms appropriate to each underlying civil rights statute, rather than to create a new and confusing civil rights regulatory framework specific to the enforcement of Section 1557.

h. Notices of Nondiscrimination Rights and Statement of Nondiscrimination Under the 2016 Rule (Repeal of § 92.8 of the 2016 Rule)

The Department proposed to repeal § 92.8 of the 2016 Rule, which required a notice informing individuals about nondiscrimination and accessibility requirements, such as the sample notice and nondiscrimination statement at Appendix A to Part 92.

Comment: Some commenters contended that HHS did not consider how the removal of the 2016 Rule's notice provisions may result in decreased access to, and utilization of, healthcare by people with disabilities, people with LEP, older adults, people who are LGBT, and other vulnerable populations. These commenters argued that with the notice provision's removal, these protected populations will be limited in knowing their rights under Federal civil rights laws, and in knowing how to file complaints with OCR if faced with discrimination in a healthcare setting. Others stated that the Department did not provide an evidentiary basis for what it deemed would be a ''negligible'' impact on people with LEP or ''additional societal costs'' as a result of removing the notice provisions. Commenters proposed that instead of eliminating the notice provision, the Department should consider requiring covered entities to provide notice on an annual basis, when updated, and upon request, in order to harmonize with the Health Insurance Portability and Accountability Act (HIPAA)'s annual notice requirements. Other commenters similarly proposed that the Department should consider specifying a number of times that a covered entity should send notice to individuals over the course of a year.

Response: The regulations implementing Section 1557's four underlying statutes already contain notice provisions.[257] The language in the 2016 Rule to this effect was unnecessary.

Individuals belonging to any protected category under Section 1557, including those with disabilities or LEP, remain covered under existing standards regarding notice. The Department is unaware of data suggesting that those regulations have been or are inadequate to their purpose of making individuals aware of their civil rights. To the extent that it discovered such data, it would consider revising each regulation as appropriate.

Each of the relevant underlying regulations has its own unique standards on providing notice, tailored to the purposes of each civil rights statute.[258] Compressing these into a single standard under the 2016 Rule has led to an unjustifiable burden and understandable confusion. The Department's estimates of regulatory burden are discussed in the RIA.

Comment: Some commenters stated the Department should clarify when the notice and taglines requirements will no longer be effective with respect to timeframes such as open enrollment for Exchanges, employer-sponsored plans, and Medicare. Most of these communications are subject to the current notice and taglines requirements under the 2016 Rule. Commenters sought clarification from the Department as to whether OCR will enforce the notice and taglines requirement against any covered entity from the date of the proposed rule (June 14, 2019).

Response: The changes made in this final rule will be effective 60 days from the publication of this final rule in the **Federal Register**. The 2016 Rule is in effect until that time, except as enjoined or vacated by courts.

Comment: Several commenters requested that the Department retain parts of § 92.8 of the 2016 Rule that require the designation of a responsible employee and grievance procedures, and the text of sample grievance procedures in Appendix C to Part 92. They said that retaining these provisions would increase access to healthcare and retain uniform responsible employee and grievance procedures.

Response: The Department believes it is appropriate to rely on the regulatory framework that has already been set forth for Section 1557's four underlying statutes. To the extent that those implementing regulations have responsible employee and grievance procedures, they are sufficient for enforcement of Section 1557.

i. Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, the Department finalizes § 92.5, and the proposed repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule, without change.

(7) Relationship to Other Laws in Proposed § 92.6, and Repeal of § 92.2(b) and 92.3 of the 2016 Rule

The Department proposed to repeal §§ 92.2(b) and 92.3 of the 2016 Rule, which addressed the application and relationship of Section 1557 and the 2016 Rule to other laws. The Department proposed instead a new § 92.6. The new § 92.6(a) states that nothing in the 1557 regulations shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards applicable under Title VI, Title VII, Title IX, the Age Act, or Section 504, or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2. The new § 92.6(b) states that insofar as the application of any requirement under the Section 1557 regulations 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

[256] *See* 45 CFR 84.4(b)(1)(v) (Section 504); § 86.31(b)(6), as finalized here (Title IX).

[257] *See* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act).

[258] Title VI, 45 CFR 80.6(d), and the Age Act, 45 CFR 91.32, contain general requirements to provide notice. Section 504 requires more: A covered entity must ''take appropriate initial and continuing steps to notify [individuals] that it does not discriminate on the basis of [disability]'' and include this information in its ''recruitment materials and publications.'' 45 CFR 84.8. Title IX goes even further: A covered entity must ''prominently'' display its notice of nondiscrimination in ''each announcement, bulletin, catalog, or application form which it makes available to any [covered person], or which is otherwise used in connection with the recruitment of students or employees'' and not ''distribute a publication . . . which suggests, by text or illustration, that such [covered entity] treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by [Title IX].'' 45 CFR 86.9.

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.

a. Conscience Laws

Comment: Some commenters supported revising the Section 1557 Rule to explicitly identify the Federal public consensus that conscience statutes reflect, in order to ensure appropriate protection for all civil rights. Some noted that the Coats-Snowe and Church Amendments were passed by Congress and signed into law on a bipartisan basis, reflecting explicit protections from discrimination on the Federal, State, or local level if healthcare providers or hospitals seek to be exempted from participation in the performance or training for abortions.

Some commenters supported including references to conscience and religious freedom laws in § 92.6(b), stating that protecting the conscience rights of healthcare providers also protects patients by protecting trust between patients and providers, and allowing providers who entered healthcare on the basis of moral convictions to serve those who are ill consistent with that ethic. They also stated that providers must exercise professional judgment as to what constitutes the best interest of the patient. Commenters stated that respect for the autonomy of the patient should not be misconstrued to create coercive obligations on providers overriding the best interest of the patient. Some stated that the 2016 Rule resulted in a ''Hobson's choice'' of options for certain providers, who were required under the rule to either violate their ethical pledges to Do No Harm or their longstanding oaths as physicians, or comply with the 2016 Rule and be forced to perform abortions. Some commenters also suggested that if those providers complied with laws like Title VII and conscience laws that require religious accommodation, they could risk noncompliance with the 2016 Rule, or vice versa. Some of those commenters contended that coercing providers to compromise their moral integrity negatively impacts both provider and patient, and ultimately hurts the provider's ability to provide patient care. If facing the threat of coercion, such commenters said, providers will continually face escalating moral dilemmas in the practice of their job, resulting in stress and burnout in a time when physician shortages are already increasing.

Other commenters opposed the language in § 92.6(b), saying that the proposed rule construes the Federal conscience protections more broadly than existing law allows. They contended conscience protections and religious liberty are meant for individuals, not entities, and that healthcare systems and entities cannot have the right of conscience, because the notion of conscience is limited to individuals. Some commenters also recommended that instead of removing gender identity and termination of pregnancy language and having the language in § 92.6(b) concerning conscience and religious freedom statutes, the Department should merely insert a narrow religious exemption, for they asserted that preventing discrimination on the basis of gender identity or termination of pregnancy is more critical than religious freedom rights, which should be more heavily scrutinized for pretextual discrimination. Other commenters stated that conscience and religious protections under the current statutes are sufficient and incorporating conscience or religious exemptions is unnecessary. Some opposed referring to the Coats-Snowe Amendment in § 92.6(b), saying that it would allow healthcare providers to decline to make medical care available to any patient based on personal beliefs. Some added that the Department does not have the authority to interpret statutes such as the Coats-Snowe Amendment to limit or supersede Section 1557, which should be seen as controlling law. One commenter stated that Federal conscience statutes are not applicable to the ACA because they are not mentioned in the ACA.

Response: Section 1557 and the ACA did not repeal any Federal conscience law. Indeed, ACA § 1303 specifically provides that ''[n]othing in [the ACA] shall be construed to have any effect on Federal laws regarding—(i) conscience 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 to provide or participate in training to provide abortion.'' 42 U.S.C. 8023(c)(2). At the time of its passage, the President stated that ''[u]nder the [ACA], longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact and new protections prohibit discrimination against healthcare facilities and healthcare providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.'' [259] New law is to be interpreted consistently with existing law wherever possible, and the Department sees no conflict between Section 1557 and preexisting Federal conscience statutes.

This final rule emphasizes that the Section 1557 regulation will be implemented consistent with various statutes enacted by Congress, including conscience and religious freedom statutes. This should not be a controversial statement, nor should it even be necessary to add, as the Department is always obligated to comply with relevant Federal statutes. But the fact that so many commenters found this provision objectionable is itself a reminder of why such a provision is needed. The fact that the 2016 Rule was the subject of litigation and injunctive relief, in part because of plaintiffs' claim that the 2016 Rule did not clearly state that it would be enforced consistent with conscience and religious freedom statutes, is also a reason the Department believes it is appropriate to make the issue clearer in this final rule. This final rule does not purport to construe the statutes referenced in this section, so it cannot be construing them too broadly (or too narrowly). It would be inappropriate to replace § 92.6(b)'s language with a religious exemption, whether narrow or broad, because § 92.6(b) neither adds to nor takes away from the conscience and religious freedom statutory language that Congress has enacted.

Commenters who discuss the gender identity and termination of pregnancy provisions of the 2016 Rule in this context are confusing two different issues. As stated above, this final rule eliminates the 2016 Rule's provisions related to gender identity for numerous

[259] Executive Order 13535, ''Patient Protection and Affordable Care Act's Consistency with Longstanding Restrictions on the Use of Federal Funds for Abortion'' (March 24, 2010).

legal and policy reasons that have nothing to do with conscience protection, and it eliminates the 2016 Rule's provisions on termination of pregnancy because they failed to incorporate Title IX's abortion-neutrality language (which goes much farther than any mere protection for individual conscientious objectors). In neither case could the Department's concerns have been adequately addressed by permitting individuals to claim a conscientious exemption from those objectionable provisions.

Comment: Many providers with conscientious or religious concerns stated that their medical judgment is based upon a review of the clinical evidence, and that medical ethics requires that they act in accordance with their best medical judgment. For example, some commenters contended that they have practices, such as in the obstetrics and gynecology field, which are specialized to the biological sex of females based on a binary distinction between males and females. Others had objections because of their moral and religious convictions concerning specific procedures that they sincerely believed, both in their medical judgment and ethically, would endanger the health and wellbeing of a person.

Response: By respecting medical professionals' judgment, the Department protects their right and responsibility to follow medical ethics in treating patients to the best of their ability. In their objections to abortion, sex-reassignment procedures, or other treatments covered by the 2016 Rule, some providers assert that not only their medical judgment but also their conscientious or religious beliefs would be burdened by such procedures. The Department believes that the best way to avoid such burdens on conscience is, instead of requiring individual objectors to assert claims under RFRA or other applicable laws, to avoid regulatory requirements that would have forced them to provide such procedures in the first place, as well as to ensure that remaining requirements are interpreted consonant with the applicable Federal conscience statutes.[260] This will protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high-quality and conscientious care that they deserve.

Comment: Some commenters argued that religious or conscience exemptions were used as a pretext to conceal animus against LGBT individuals. Commenters expressed concerns that the proposed rule would improperly prioritize conscience and religious freedom rights over LGBT rights or civil rights in general. However, others, such as hospital associations that expressed support for care regardless of gender identity and sexual orientation, explained that they also support appropriate protections for the reasonable accommodation of a nurse or other provider who may assert a sincere conscientious objection to participating in a particular medical procedure. Other providers stated that the exemption they seek is from providing certain treatments, not from treating certain patients. Some submitted their hospital nondiscrimination policies, contending those policies do not include blanket denial of healthcare treatment for LGBT individuals, and in many cases expressly prohibit discrimination on the basis of gender identity or sexual orientation, but that they nonetheless seek limited exemptions on the basis of sincerely held religious and moral convictions. Some individual, institutional, and religious groups affiliated with healthcare providers also provided comments stating that both in policy and in practice, they have never refused to care for a patient on the grounds of their identity as an LGBT individual. They stated that they object to being required to perform services that violate sound medical judgment, ethical convictions, or religious beliefs about the dignity of human beings. Commenters also submitted surveys finding healthcare professionals experienced pressure, coercion or punishment for not participating in training, performing a procedure, or writing a prescription when they had medical or scientific objections.

Response: The Department recognizes that members of the public hold different opinions concerning conscience and religious freedom laws and their interplay with various health contexts, including with respect to LGBT concerns. This final rule does not, however, create any new conscience or religious freedom exemptions beyond what Congress has already enacted.

Comment: Some commenters contend that women of color are more likely to rely on religious hospitals to receive care, and thus women of color will be more likely to be affected by religious exemptions that allow religious hospitals to deny certain reproductive care. Others opposed inclusion of references to conscience and religious freedom laws, stating that the danger of losing Federal funds is the only incentive for covered entities to offer more abortion, contraception, sterilization, gender identity affirming, or sex reassignment services. Other commenters stated that conscience laws were intended to protect health professionals from precisely that form of government coercion.

Some commenters stated that the proposed rule, in particular concerning the Church Amendments, 42 U.S.C. 300a–7, is inconsistent with EMTALA, because the conscience exemptions would deny emergency and stabilizing care, including with respect to abortion or sterilization. Other commenters stated that the rule is consistent with EMTALA, because EMTALA requires protection of the ''unborn child.''

Response: The Department is not aware of any instance to date where a facility required to provide emergency care under EMTALA was unable to do so because of objections protected by the Church Amendments. This final rule does not adopt any stance on how hypothetical conflicts between the Church Amendments and EMTALA ought to be resolved. The Department intends to read every law passed by Congress in harmony to the fullest extent possible, so that all laws are given their fullest possible effect. Commenters' other policy concerns about the possible healthcare effects of the conscience laws are among the many complicated factors that Congress had to balance in the texts of the separate statutes, and it is not the Department's job to overturn the results of that legislative process.

Comment: One commenter compared the proposed rule with the 2019 Conscience Rule and alleged that the Department's recent actions of decreasing protections for patients and increasing protections for providers run contrary to actual public sentiment. The commenter alleged that between 2008 and January 2018, the Department received fewer than 50 complaints regarding violations of Federal religious or conscience statutes while receiving 30,000 complaints of other civil rights discrimination in 2017 alone. Other commenters stated that the 2019 Conscience Rule violates EMTALA, and results in the denial of transition-related surgeries or abortion services in emergencies, because conscience statutes allow exemptions from performance of sterilizations or abortions. Commenters also recommended that the Department delay finalizing the proposed rule pending the outcome of litigation challenging the 2019 Conscience Rule, in order to provide clarity and finality, and to reduce litigation risk as regards the construction of Section 1557 with conscience statutes.

[260] *See California* v. *Azar,* at *24 (''HHS acted well within its authority in deciding how best to avoid conflict with the Federal conscience laws.'').

Response: This final rule is separate from the 2019 Conscience Rule. It does not implement that rule, and it does not implement the statutes implemented by that rule. Several courts have vacated the 2019 Conscience Rule before its effective date, but none of those courts issued any order against the conscience statutes themselves,[261] which the Conscience Rule sought to implement and which this final rule references. Because this final rule does not refer to or rely on the 2019 Conscience Rule, there is no reason to delay finalization of this rule pending further litigation over the 2019 Conscience Rule.

b. Religious Freedom Restoration Act

Comment: Some commenters said that the proposed rule's inclusion of the Religious Freedom Restoration Act (''RFRA'') in § 92.6(b) was unclear and confusing. Others said that it should be excluded because it would allow providers to deny needed healthcare. Other commenters supported inclusion of RFRA, agreeing that it is an important protection for religious conscience from government-imposed burdens. Commenters also pointed out that the Federal government has clearly articulated its commitment to RFRA and religious freedom laws under a recent executive order [262] and the subsequent Attorney General Memorandum [263] to executive departments and agencies that ''Congress has taken special care with respect to programs touching on abortion, sterilization, and other procedures that may raise religious conscience protections.'' [264] One commenter supported the Department's explicit acknowledgment that Section 1557 is subject to RFRA, stating that religious organizations have had to repeatedly go to court to vindicate their conscience rights against the Department's enforcement of the 2016 Rule. Others said that referring to RFRA accurately reflects statutory text and Congressional intent, and would correct a legal misinterpretation of Section 1557 that has been recognized as such by the *Franciscan Alliance* court.

Response: Congress explicitly stated that RFRA applies to ''all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993 . . . unless such law explicitly excludes such application by reference to this chapter.'' [265] Section 1557 does not explicitly exclude such application, so the Department is bound to enforce Section 1557 in compliance with RFRA. The Department agrees with the court in *Franciscan Alliance* that particular provisions in the 2016 Rule violated RFRA as applied to private plaintiffs.[266] In order to ensure that Section 1557 regulations are now interpreted consistently with, and implemented in compliance with, RFRA, the Department considers it appropriate to specify this explicitly.

Comment: Some commenters stated that the text of the Section 1557 statute does not contain a religious exemption, and therefore asked the Department not to include a religious exemption, either explicitly or by reference in § 92.6(b). Other commenters stated that exemptions on religious bases should be blanket exemptions, not case-by-case exemptions as outlined in RFRA.

Response: This final rule does not craft a religious exemption to Section 1557. Congress has already created various religious and conscience protections in healthcare by enacting several statutes, including RFRA, healthcare conscience statutes, and the religious organization exception in Title IX. This final rule simply states that the Section 1557 regulation will be implemented consistent with those statutes.

c. Title IX

Comment: Some commenters opposed including reference to the Title IX statutory religious exemption in § 92.6(b). They said that Section 1557 does not require or authorize Title IX religious or abortion exemptions, because these are limited to educational institutions, and are improper in the healthcare context. Others expressed concern that Section 1557 and Title IX would be subject to exemptions that HHS does not apply to its rules enforcing Title VI.

Other commenters stated that it is unnecessary and unwise to change the standard for the religious exemption under Title IX, and pointed to the legislative history of Title IX, where the Conference Committee rejected an amendment proposed by Senator Hatch to loosen the standard for the religious exemption. Commenters stated that § 92.101(c) of the 2016 Rule took an inconsistent analysis by failing to incorporate Title IX's religious and abortion exemptions, despite incorporating exemptions from the other three Federal civil rights laws referenced in Section 1557.

Still other commenters stated that the Title IX exemption should not apply broadly to large religious institutional healthcare facilities, or that conscience protections and religious liberty cannot apply to institutions like hospitals or healthcare systems because they cannot have the right of conscience: They suggested that conscience is limited to individuals and that an institution is not a person. Other commenters disagreed and pointed to legislative history to recognize that the protections under Title IX's religious exemption are not just for individuals but for institutions.

Response: The text of Title IX applies its religious exemption to institutions, so there should be no question that religious exemptions can apply to institutions as well as individuals.[267] As discussed above regarding termination of pregnancy, the *Franciscan Alliance* court vacated portions of the 2016 Rule for failing to incorporate Title IX's exemption for religious institutions. More generally, the Supreme Court in *Burwell* v. *Hobby Lobby* held that RFRA can apply to for-profit corporations. 573 U.S. 682 (2014). And that holding parallels other Supreme Court precedent making clear that organizations may engage in exercises of religion protected by the First Amendment. *See, e.g., Masterpiece Cakeshop, Ltd.* v. *Colo. Civil Rights Comm'n,* 138 S. Ct. 1719, 1732 (2018); *Hosanna-Tabor Evangelical Lutheran Church & Sch.* v. *EEOC,* 565 U.S. 171, 199 (2012); *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah,* 508 U.S. 520, 525–26, 547 (1993).

Under the Civil Rights Restoration Act amendments to Title IX, the Title IX religious exemption is no longer limited to educational institutions controlled by religious organizations: Any educational operation of an entity may be exempt from Title IX due to control by a religious organization.[268] Section 1557

[261] *See New York* v. *United States Dep't of Health & Human Servs.,* 414 F. Supp. 3d 475 (S.D.N.Y. 2019); *City & Cty. of San Francisco* v. *Azar,* 411 F. Supp. 3d 1001 (N.D. Cal. 2019); *Washington* v. *Azar,* No. 2:19–CV–00183–SAB, 2019 WL 6219541 (E.D. Wash. Nov. 21, 2019).

[262] Executive Order 13798 on Promoting Free Speech and Religious Liberty, 82 FR 21675 (May 4, 2017).

[263] Memorandum of the Attorney General (Oct. 6, 2017), *https://www.justice.gov/opa/press-release/file/1001891/download.*

[264] *Id.*

[265] 42 U.S.C. 2000bb–3.

[266] *Franciscan Alliance,* 2019 WL 5157100 at *9 (''[T]he Court holds that the Rule, which expressly prohibits religious exemptions, substantially burdens Private Plaintiffs' religious exercise in violation of RFRA.'')

[267] *See* 20 U.S.C. 1681(a)(3) (''this section 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''); 20 U.S.C. 1687(4) (excluding ''any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization'').

[268] *Id.*

incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions and abortion neutrality. Although much of Title VI case law can be applied to Title IX situations, the parallel is not perfect because Title IX contains several important statutory exemptions that are absent from Title VI. These are mentioned above in the section on discrimination on the basis of sex.[269]

Comment: Commenters stated that adding the Title IX exemption for religious entities violates the Establishment Clause, because it would force third parties to subsidize or bear the costs of religious exercise, citing *Cutter* v. *Wilkson,* 544 U.S. 709 (2005), *Lee* v. *Weisman,* 505 U.S. 577 (1992), and *Estate of Thornton* v. *Caldor, Inc.* 472 U.S. 703 (1985). Commenters indicated that religious exemptions must take an adequate account of the burdens a requested accommodation may impose on nonbeneficiaries. Commenters similarly suggested that the rule's requirement that the Section 1557 rule be implemented consistent with RFRA would violate the Establishment Clause and should be limited to instances where no third party is harmed by application of RFRA.

Response: Neither RFRA (as applied to Federal government actions), nor Title IX's statutory exemptions, have ever been held unconstitutional by the Supreme Court. The Court has upheld Title VII's statutory exemption for religious organizations,[270] and has denied that statutory exemptions of this type violate the Establishment Clause.[271] The Department will comply with all relevant court rulings.

d. Other Laws and Cases

Comment: The Department received comments supporting the express mention of Section 1303 of the ACA [272] in proposed § 92.6. These commenters contended that this helps clarify the prohibition on mandating QHPs to provide abortions, and that it could not have been Congress's intent to mandate abortion coverage in Section 1557. Section 1303 expressly leaves it up to issuers of health plans to decide not to cover abortion. Other comments stated that Section 1303 should not be expressly mentioned in this rule and that termination of pregnancy should remain as a prohibited basis of discrimination under the Section 1557 rule, notwithstanding Section 1303.

Response: In Section 1303, Congress specified that nothing in the ACA (therefore including Section 1557) ''shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion'' (emphasis added). The Department considers it appropriate to finalize § 92.6 to indicate that the Section 1557 regulation will be implemented consistent with Section 1303, as that provision is relevant to the interpretation of the Federal laws that Section 1557 incorporates by reference.

Comment: The Department received comments from State public officials raising concerns about the 2016 Rule's constitutionality. State public officials contended that the 2016 Rule violated the Spending Clause because the Federal government did not provide adequate notice by clear statement and opportunity to agree to the Section 1557 Rule's new conditions on receipt of Federal financial assistance. States also raised objections under the Eleventh Amendment to the Department-initiated Section 1557 enforcement actions. States identified their obligation to protect the First Amendment rights to free exercise of religion of their citizenry. However, these State commenters noted that the proposed rule's removal of the definition of ''on the basis of sex,'' and the addition of the religious and abortion exemptions, would address these concerns.

Other commenters stated that when the Department said in the 2019 NPRM that State and local entities are better suited than the Federal government to address gender identity discrimination, this was contrary to constitutional law principles and undermined the right to be free from discrimination.

Response: The Department is not aware of any Supreme Court precedent that would call into question the constitutionality of its reasoning about federalism as laid out in the 2019 NPRM.[273] The Department believes that this final rule resolves the concerns States had about the 2016 Rule's constitutionality.

Comment: Some comments from State public officials stated that the 2016 Rule conflicted with State laws on religious accommodations and independent medical judgment of healthcare providers. A different group of State public officials submitted a separate joint comment stating that their States' civil rights legislation and/or regulations prohibited discrimination on the basis of gender identity or sexual orientation, and that the proposed rule would remove the consistency of their laws with the 2016 Rule. They argued that State insurance agencies acted first to promulgate regulations after passage of Section 1557 in 2010, assuming that Section 1557 prohibited gender identity discrimination. Some States also said that the proposed rule's incorporation of Federal conscience statutes would result in conflict with State laws, or with other Department rules requiring covered entities to provide care to all (*e.g.,* vaccination care).

Some States said that as employers they had difficulty resolving religious accommodation laws with Section 1557. Others stated they had no difficulties resolving consumer complaints of discrimination on the basis of gender identity.

Response: The Department agrees that States have a public interest in enforcement of their statutes, including conscience and religious freedom statutes. This final rule respects Federalism: It neither interferes with State laws on conscience protections and medical judgment, nor does it interfere with State laws that provide additional protections (so long as these do not violate other Federal statutes). The rule also explicitly provides that Section 1557 will not be taken to supersede State laws that provide additional protections against discrimination on the enumerated grounds. The Department is not aware of actual, as opposed to hypothetical, conflicts between the statutes incorporated here and other laws or

[269] 20 U.S.C. 1681(a)(6)(B); 34 CFR 106 *et seq.*

[270] *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 338–40 (1987); *see also Walz* v. *Tax Commn. of City of New York,* 397 U.S. 664 (1970) (upholding the constitutionality of a state's statutory property tax exemption for religious organizations); *Id.* at 675 (''The grant of a tax exemption is not sponsorship since the government does not transfer part of its revenue to churches but simply abstains from demanding that the church support the state. No one has ever suggested that tax exemption has converted libraries, art galleries, or hospitals into arms of the state or put employees 'on the public payroll.' There is no genuine nexus between tax exemption and establishment of religion.'').

[271] *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* at 336–37 (''We agree with the District Court that this purpose does not violate the Establishment Clause. . . . A law is not unconstitutional simply because it allows churches to advance religion, which is their very purpose.''); *Id.* at 339 (''It cannot be seriously contended that [Title VII's statutory exemption] impermissibly entangles church and state; the statute effectuates a more complete separation of the two and avoids the kind of intrusive inquiry into religious belief that the District Court engaged in in this case.'').

[272] 42 U.S.C. 18023.

[273] *See* 84 at 27857 (2019 NPRM discussion of ''Sensitive Balancing of Competing Interests at the Local Level'' at Part g).

regulations that the Department enforces.

Comment: A commenter supported including the reference to Section 1553 of the ACA in § 92.6 in order to protect nurses who have objections to participating in assisted suicide, promote trust in the nurse-patient relationship, and keep the profession open to candidates who want to serve as nurses but object to participation in assisted suicide.

Commenters supported the proposal's specification that the proposed regulation not be applied in a manner that conflicts with or supersedes exemptions, rights, or protections contained in several civil rights statutes, such as the Architectural Barriers Act of 1968, the Americans with Disabilities Act of 1990 (as amended by the Americans with Disabilities Act Amendments Act of 2008), and Section 508 of the Rehabilitation Act of 1973.

Some commenters requested that the word ''obligations'' be added in order to specify that the proposed regulation not be applied in a manner that conflicts with or supersedes the exemptions, rights, protections or obligations contained in several civil rights statutes. This addition would help clarify that this consideration is intended to help reduce redundancy, compliance burdens, and confusion for healthcare providers.

Response: The Department appreciates all these comments in support of the proposed rule. The Department declines to add the word ''obligations,'' as the final rule's language adequately addresses its interaction with other civil rights statutes.

Comment: One commenter noted that a number of provisions in the proposed rule seem to contradict portions of the recent Conscience Rule published by the Department.[274] In particular, this proposed rule eliminates and narrows definitions advanced by the 2016 Rule, while the Conscience Rule expands definitions and protections. This proposed rule seeks to drastically cut costs of enforcement by eliminating notice and taglines requirements and other costs for providers, while the Conscience Rule will impose new costs on providers and individuals. Finally, this proposed rule and the Conscience Rule use different definitions to define health programs and activities.

Response: The 2019 Conscience Rule and this final rule rely on different statutes, and different underlying regulations for those statutes, so it is not surprising that there should be differences between their respective definitions and protections. The four civil rights statutes underlying Section 1557 have implementing regulations containing appropriate definitions, protections, and enforcement mechanisms. As explained herein, the Department has now deemed most of the parallel provisions in the 2016 Rule to be unnecessary, superfluous, or unduly burdensome. Therefore the Department considers it appropriate to finalize a Section 1557 rule that is shorter than the 2016 Rule and relies more substantially on those underlying regulations. In contrast, the 2019 Conscience Rule (which has been vacated and is subject to pending litigation) modified previous regulations that are only three sentences long, and that lack the kinds of definitions and enforcement mechanisms found in regulations implementing other civil rights laws enforced by the Department. In promulgating the 2019 Conscience Rule, the Department concluded more extensive regulations were needed in the absence of existing regulations containing such provisions.

Comment: One commenter stated that the proposed rule's changes to the relationship to other laws section at § 92.6 are contrary to the requirements of Section 1557, because the 2016 Rule stated that neither it nor Section 1557 would apply a lesser standard than Title VI, Title IX, Section 504, or the Age Act. In contrast, the proposed rule expressly states that application of the proposed rule will not be required if the proposed rule violates, departs from, or contradicts a number of other Federal civil rights laws.

Response: The Department seeks to give all laws their fullest possible effect. It does not believe that the other laws referenced at § 92.6 are generally in conflict with Title VI, Title IX, Section 504, or the Age Act, except to the extent that some of them (*e.g.,* RFRA) may be specifically designed to limit the applicability of other Federal laws and governmental actions.

e. Summary of Regulatory Changes

For the reasons described in the proposed rule and having considered the comments received, the Department finalizes § 92.6 and repeals §§ 92.2(b) and 92.3 of the 2016 Rule without change.

C. Section 1557 Regulation, Subpart B: Specific Applications to Health Programs or Activities (Sections 92.201–92.205 of the 2016 Rule)

The Department requested comment on the proposed retention and modification of the provisions in Subpart B of the Section 1557 regulation, which imposes specific requirements on covered entities as regards individuals with LEP or disabilities.

(1) Meaningful Access for Individuals With Limited English Proficiency (45 CFR 92.101)

The Department proposed § 92.101(a), which states that any entity operating or administering a health program or activity subject to the Section 1557 regulation is obligated to take reasonable steps to ensure meaningful access to such programs or activities by LEP individuals. It also proposed § 92.101(b), which states that OCR may assess how an entity 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.

Section § 92.101(b) retains many of the 2016 Rule's provisions related to access for LEP individuals. It removes definitions of the terms ''qualified bilingual/multilingual staff'' and ''individual with limited English proficiency,'' but the 2019 NPRM expressed the Department's commitment to interpreting those terms naturally and consistently with the 2016 Rule.[275] It also repeals the 2016 Rule's definition of ''national origin.''

The Department requested comment on whether 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 that only receive HHS funding for human services, would cause problems or confusion, and (if so) whether this might warrant amendments to the Department's Title VI regulation.

Comment: In response to the Department's request for comment concerning possible amendments to the underlying civil rights regulations, some commenters said that they were unable to provide meaningful comments without HHS first providing explanations and rationale for any proposed changes, and that unanticipated changes could not be

[274] 45 CFR part 88.

[275] 85 FR 27860–61, 27866.

made in a final rule without first giving the public an opportunity to comment on those proposed changes.

Response: The Department did not propose changes to regulations other than those finalized here, but simply invited comment on whether to consider doing so. In this final rule, the Department does not implement any such changes, and in this respect finalizes the proposed rule without change. The Department here finalizes only those changes proposed in the 2019 NPRM (with minor and primarily technical changes to these).

Comment: Some commenters opposed the proposed rule's revisions to the requirements for meaningful access for LEP individuals, arguing that they weaken nondiscrimination requirements. These commenters noted that instead of requiring covered entities to take reasonable steps to provide meaningful access for *each* ''LEP individual eligible to be served or likely to be encountered,'' the proposed rule only requires covered entities to take steps to ensure meaningful access for ''LEP individuals'' generally. These commenters contend that this change will result in a number of LEP individuals unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals. Many commenters stated that lack of understanding in a medical setting could cause harm and possibly death to patients with LEP. One commenter emphasized the facilitative role that interpreters play to decrease risk associated with miscommunication between patients and providers. A commenter expressed concerns that healthcare services would dramatically decrease for individuals with LEP who are unable to access an interpreter. Another commenter objected to the notion that oral interpretation for patients would not be required. Some commenters also oppose the replacement of the 2016 Rule's two-factor test with a four-factor test. One commenter recommended replacing the term ''reasonable'' in the Department's LEP Guidance meaningful access standard with the term ''all,'' saying that the word ''reasonable'' leaves too much room for ambiguity in its application.

Response: The 2016 Rule imposed a stringent requirement on covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered. This provision could potentially be interpreted to require a covered entity to provide language assistance services to every LEP individual it comes into contact with. This final rule instead follows DOJ's longstanding LEP guidance (under Executive Order 13166), and HHS's corresponding LEP guidance from 2003, by saying that a covered entity under Title VI must take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals.[276] Adopting this language would apply the same standard to both health and human services programs within the Department, and would conform to the other Federal agencies that follow DOJ's LEP Guidance, consistent with its civil-rights coordinating authority. Because Section 1557 incorporates the enforcement mechanisms available under Title VI (which encompasses LEP status under *Lau* v. *Nichols*),[277] it is appropriate for this final rule to adopt the Title VI standard requiring reasonable steps to ensure meaningful access.

This final rule also incorporates the four-factor test found in the DOJ LEP Guidance and reiterated in the Department's own 2003 LEP Guidance. That test is ''designed to be a flexible and fact-dependent standard,'' [278] and is meant to strike a balance that ensures meaningful access by LEP individuals to critical services while not imposing undue burdens on small businesses, small local governments, or small nonprofits. As the 2019 NPRM made clear, an individualized case-by-case assessment of the four factors is the starting point for exercising the Department's enforcement discretion in language access cases.[279]

This final rule retains, and the Department will vigorously enforce, the underlying legal standard of Title VI: Recipients are prohibited from utilizing criteria or methods of administration which have the effect of subjecting individuals to discrimination on the basis of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the program with respect to individuals on the basis of their race, color, or national origin. Entities that utilize such criteria or methods of administration have failed to take reasonable steps to ensure meaningful access to their programs by individuals with LEP and are operating their programs in violation of this final rule's prohibition against discrimination on the basis of national origin. All covered entities remain obligated to submit assurances that they will comply with Title VI and all other relevant civil rights law.[280]

The language access provisions in this final rule are consistent with Title VI enforcement mechanisms and with the Department's longstanding guidance. Title VI enforcement mechanisms are broadly known to the regulated community, and the HHS LEP Guidance has been effective in helping covered entities comply with the statute and implementing regulations. The Department regards the four-factor test, employed since 2003, as the best way of balancing the relevant factors in ensuring nondiscrimination on the basis of national origin. Under this final rule, the Department's LEP Guidance will help covered entities assess their programs using the four factors to ensure meaningful access to their programs by individuals with LEP. By eliminating confusion, inconsistency, redundancy, and unnecessarily burdensome compliance costs, this final rule applies proven enforcement mechanisms and guidance to ensure access to covered programs by individuals with LEP.

Comment: Commenters stated that the proposed rule significantly reduces the administrative burden placed on providers. For example, the proposed rule will allow retail pharmacies to provide patients with better quality of care in a more efficient manner. Another comment emphasized that under the 2016 Rule, providers are required to physically post the information at their facilities, on their websites, and in any ''significant'' publications and communications. This example underscored that the term ''significant'' has never been defined by OCR, which has resulted in providers using taglines notices in nearly every document provided to patients. This practice was described as administratively burdensome and counterproductive, because patients already receive numerous notices mandated by the Department. Another commenter expressed support for the proposed rule's empowerment of individual entities to take reasonable steps to ensure meaningful access.

Response: The Department agrees, and recognizes the burdens imposed by the 2016 Rule's requirement to post notices and taglines in all significant communications and publications, as well as by the difficulty of determining the meaning of ''significant'' with

[276] *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).

[277] 414 U.S. 563 (1974).

[278] 68 FR 47314 (Aug. 8, 2003) (HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

[279] 84 FR 27865 (June 14, 2019).

[280] *See* 84 FR 27860.

respect to the numerous and diverse types of programs covered by this final rule. These requirements were difficult for covered entities to implement due to different and overlapping language access requirements imposed by the Federal government and by many States.[281] Stakeholders have informed the Department that the repetitive nature of these requirements dilutes the messages contained in significant communications to the point that some recipients may be disregarding the information entirely.[282] In addition, many beneficiaries do not want to receive extra pages of information they have seen many times before, due to environmental concerns or annoyance.[283] Most significantly, the Department has found scant evidence to demonstrate that repeatedly mailing all beneficiaries of Federal and other health programs taglines with 15 or more languages is an efficient use of covered entities' language access resources when the overwhelming majority of beneficiaries speak English.[284] Savings from the notice and taglines requirements changes are described in more detail in the Regulatory Impact Analysis.

Comment: Some commenters stated that the notices and taglines requirements of the 2016 Rule are burdensome, but that the Department should consult with stakeholders to determine how to most effectively and efficiently communicate with LEP individuals, rather than repeal the requirements.

Response: The Department consulted with the public before and since issuing policy guidance to recipients on compliance with the Title VI obligation to take reasonable steps to ensure meaningful access to their programs by individuals with LEP. The Department also provided stakeholders with an opportunity to comment on the proposed rule during the public comment period.

Comment: The Department received comments opposing the proposed rule's revised § 92.101, which requires covered entities to take reasonable steps to ensure meaningful access to its programs or activities by individuals with LEP. Commenters asserted that the proposed change is contrary to congressional intent because the language in Section 1557 is clear that ''an individual shall not'' be subject to discrimination on the prohibited grounds. Others stated that the proposed § 92.101 inappropriately changes the Section 1557 regulation language and shifts the focus of the regulation from an individual's rights to the covered entity's programs or activities, thus weakening meaningful access and running contrary to the text of Section 1557.

Still others recommended that—through sub-regulatory guidance—the Department should communicate to providers the flexibility of the LEP access requirement.

Response: This final rule fully retains all protections offered by Section 1557, and it does not shift any focus from an individual's rights to the covered entity's programs or activities. It ensures that covered entities do not use their programs or activities to discriminate on the basis of any individual's national origin, which includes (under *Lau's* disparate impact analysis) requiring those entities to provide reasonable access to LEP individuals.

Comment: The Department received comments asserting that language assistance is necessary for individuals with LEP to access Federally funded programs and activities in the healthcare system. Several commenters argued that adequate translation services are a civil right and an important tool for informing individuals with LEP of their healthcare rights. One commenter also expressed concern that informed consent is compromised when a language barrier prevents a patient from understanding what he or she is consenting to. Many commenters also said that individuals with LEP face unique challenges in healthcare that are mitigated by language access services, and that the proposed rule might weaken access by patients with LEP to quality healthcare, resulting in patients' avoiding or postponing the medical care they require out of fear of discrimination or mistreatment due to their national origin or the language they speak.

Response: The Department strongly agrees that language assistance is often vital for ensuring access to Federally funded programs and activities in the healthcare system by individuals with LEP. The Department believes this final rule highlights its commitment to ensuring that individuals with LEP receive language access services that are appropriate under the circumstances and consistent with longstanding enforcement mechanisms and guidance. Accordingly, this final rule clarifies throughout § 92.101 that where language assistance services are required to be offered by a covered entity, they must be no-cost, timely, and accurate; that translators or interpreters provided in order to comply with the law must meet specific minimum qualifications, including ethical principles, confidentiality, proficiency, effective interpretation, and the ability to use specialized terminology as necessary in the healthcare setting; and that a covered entity may not require an individual with LEP to bring his or her own interpreter or rely on a minor child or accompanying adult to facilitate communication, except under limited exceptions. In addition, the Department expects that the cost savings estimated below resulting from repeal of notice and taglines requirements will, where applicable, free up resources that entities can use to provide more access to LEP individuals.

Comment: A commenter said that the proposed rule weakens system-wide standards governing access to language assistance services and will

[281] *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''); 68 FR 47318 (Aug. 8, 2003)—Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (setting forth guidance on translating ''vital'' documents).

[282] *See* Aetna, ''Member Reactions to 1557 Taglines'' (Apr. 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0002;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003;* Pharmaceutical Care Management Association (May 2, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006.*

[283] *See* Aetna (May 1, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005;* Pharmaceutical Care Management Association (Mar. 27, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003.*

[284] *See* Pharmaceutical Care Management Association (Mar. 27, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003.*

disincentivize the broader system from embedding and institutionalizing LEP services.

Response: The Department knows of no evidence to support this assertion and considers it an improbable one, as this final rule simply applies the longstanding and well-known enforcement mechanisms of Title VI that have proven effective over time in ensuring access by individuals with LEP to covered programs.

Comment: Commenters said that it would be beneficial if the Department contacted providers with educational documents outlining the requirements under the proposed rule.

Response: It is not Department practice to reach out to all covered entities individually upon every regulatory change. At the same time, OCR does engage in various kinds of outreach to the regulated community. The proposed rule was published in the **Federal Register** and publicized on OCR's website, and this final rule will be publicized similarly. The Department expects its changes to reduce confusion among covered entities. If OCR sees evidence that this final rule's changes are causing any new confusion, OCR will consider issuing relevant guidance and education.

Comment: The Department received comments opposing the elimination of the provision requiring the Director to consider, if relevant, whether an entity has developed and implemented an effective written language access plan appropriate to its particular circumstances. Commenters stated that language access plans are important for evaluating compliance with Section 1557 and for planning efforts to address the needs of LEP individuals.

Response: The HHS LEP Guidance continues to encourage recipients to produce language access plans, but does not require them, and offers assistance to help ensure that implementation provides meaningful access by individuals with LEP. DOJ's LEP Guidance also does not require entities to produce such a plan. This final rule brings the Department's LEP regulations into closer conformity with the DOJ guidance, while Departmental guidance continues to encourage covered entities to go beyond minimum regulatory requirements.

Comment: One commenter argued that the justifications related to costs and resource availability do not supersede the right to meaningful access for individuals with LEP. Another commenter objected to cost's being the primary determinant for compliance with the proposed rule.

Response: Cost is not the primary factor in the four-factor analysis; no single factor is determinative. The four-factor analysis does not supersede the right to meaningful access but rather helps determine when an entity has taken reasonable steps to secure that right.

Comment: Some commenters believe the four-factor analysis under § 92.101(b) is too broad, lacks clarity, does not ensure that translation and other language services are available under important medical circumstances, may require recipients to provide unnecessarily expensive services, and/or weakens recipient language access obligations to serve persons who speak infrequently encountered languages. Others said that the proposed rule does not require a medical provider to make any effort to secure translation services when a patient faces a dire medical condition. Others supported the proposed rule's changes, indicating they would provide more flexibility for covered entities while ensuring that LEP persons have meaningful access to services. Some indicated that covered entities should not be required to provide expensive forms of language assistance, such as video remote interpreting services.

Response: The Department agrees with commenters who state that the four-factor analysis is an appropriate way to allow flexibility for covered entities while ensuring meaningful access for LEP individuals. As to the specific hypothetical situations described by commenters, OCR will evaluate such situations as they are presented to OCR on a case-by-case basis. The fact-dependent nature of Title VI analysis makes it impossible to make pronouncements on such situations without all the relevant facts.

Comment: Some commenters requested that this final rule stipulate that health insurance plans are in compliance with the four-factor test if they incorporate either State LEP requirements or items 4–7 of the National Standards for Culturally and Linguistically Appropriate Services (CLAS).

Response: The ACA instructs the Department to apply to Section 1557 the enforcement mechanisms available under Title VI, which include mechanisms for enforcing language access cases. This final rule relies on longstanding Federal practice in enforcing Title VI; it is far from clear that the Department would have statutory authority to enforce the CLAS standards or State LEP requirements instead. Moreover, recipients that provide language assistance in accordance with CLAS standards and State LEP requirements may still be utilizing other methods of administration that violate the final rule.

Comment: Some commenters suggested that administrative burden would be relieved by adopting uniform language access policies with other components in the Department like CMS, arguing that it would improve patient experiences and reduce errors.

Response: Because CMS program regulations are often implemented under different statutes than are civil rights regulations, and because LEP standards under Title VI have been subject to longstanding standards under DOJ and HHS guidance, the Department does not believe it is necessary at this time to adopt uniform language access standards across these different regulations. This final rule addresses regulations under Section 1557 and the civil rights statutes it incorporates.

Comment: Some commenters argued the proposed rule weakens the qualifications for language service providers by eliminating the words ''qualified'' and ''above average familiarity with'' from the proposed description of language interpreters and translators.

Response: This final rule does not weaken any qualifications for language service providers. It continues to use the term ''qualified'' six times in its regulatory text to describe ''interpreters,'' ''translators,'' or ''staff'' as relevant. As stated in the 2019 NPRM, this final rule eliminates the term ''qualified'' from the 2016 Rule only where it was redundant and clearly implied by the context—namely, a list of the translator's/interpreter's mandatory qualifications, a list that remains unchanged from the 2016 Rule.[285] And the 2016 Rule expressly declined to include any reference to ''above average familiarity.''[286]

Comment: A commenter asserted that the proposed rule will adversely affect the patient-provider dialogue in addiction treatment programs, and underscored the importance of transparency in discussions about substance use history.

Response: The Department is not aware of any evidence to demonstrate this assertion, and believes that relying on the Department's underlying regulations and guidance will not result in such adverse effects.

Comment: Commenters expressed concern over the Department's proposal to remove requirements on video

[285] 84 FR 27860, 27866.

[286] 81 FR 31390–91.

interpreting quality standards as it relates to using video remote interpreting (VRI) services for LEP individuals or spoken language interpreting. Many commenters noted that most VRI services are done on the same equipment and through the same network and bandwidth for both spoken language and sign language, and that if these standards are removed for spoken language interpreters, there will be an unintended consequence of lower-quality VRI services for deaf and hard of hearing individuals. Other commenters noted that while they appreciated the incorporation of the ADA's definition of VRI, they opposed the removal of the technical and training requirements for the use of VRI for spoken language interpretation.

Some commenters recommended that all covered healthcare entities prioritize the use of on-site sign language interpreters, limit usage of VRI to specific situations, and maintain either a directory of local interpreters available for on-site work or a contract with an interpreter service provider to secure on-site interpreters when needed. Commenters offered detailed suggestions for regulations to limit VRI usage.

Response: In place of blanket requirements for VRI standards, this final rule adopts the four-factor analysis regarding access for LEP individuals, which will help covered entities balance competing considerations related to VRI quality standards. Where high-quality VRI is necessary to provide meaningful access to LEP persons, high-quality VRI will be required just as it was under the 2016 Rule. Furthermore, as is made clear in the next subsection (on proposed § 92.102), this final rule continues to hold covered entities to the ADA Title II standards for video interpretive services where these are needed for effective communication for deaf or hard of hearing individuals.

The Department requested comment on whether HHS's Title VI regulations at 45 CFR part 80 should be amended to address the *Lau* v. *Nichols*[287] precedent.

Comment: A commenter stated that the Department's regulations implementing Title VI do not need to be amended to address *Lau* v. *Nichols* as HHS and DOJ have followed this Supreme Court precedent for decades.

Response: The Department agrees and will continue to enforce Title VI consistent with Federal law.

In reviewing § 92.101 and public comments, the Department observed that the proposed rule inadvertently omitted the word ''or'' from the end of paragraph (b)(4)(ii)(A), concerning exceptions to the prohibition on using an adult accompanying an individual with LEP to interpret or facilitate communication. The ''or'' had been included in the parallel provision of the 2016 Rule at § 92.201(e)(2)(i); in the preamble to the proposed rule, the Department explained that it would apply those exceptions ''[l]ike the current rule'' (meaning as in § 92.201(e) of the 2016 Rule). 84 FR at 27866. To correct this, the Department finalizes § 92.101 with a technical change to insert ''or'' at the end of paragraph (b)(4)(ii)(A).

(2) Effective Communication for Individuals With Disabilities (45 CFR 92.102)

The Department proposed to retain the 2016 Rule's provisions on effective communication for individuals with disabilities. 84 FR at 27866–67.

Comment: A commenter suggested that each Section 1557 covered entity should simply comply with the standards that apply to each entity under the ADA, in order to reduce burden, confusion, and complexity.

Response: As a general matter, the Department does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557.

Comment: The Department received comments expressing concern that the proposed rule would cause major harm to people with disabilities, affecting their access to effective healthcare, especially for those individuals in underserved and rural communities. Commenters suggested that because the current rule is working as it was intended, there is not sufficient reason to reopen it. Commenters argued that the ability to effectively communicate includes the individual patient as well as the patient's family/caregivers, and that the inability to effectively communicate can have significant adverse effects on an individual's access to healthcare. Other commenters expressed support for retaining the provisions of 45 CFR 92.202 (redesignated § 92.102), regarding effective communication for individuals with disabilities. Commenters noted that effective communication is a critical component to accessing and receiving healthcare and that often covered entities rely on communication methods that are the preference of the covered entity rather than the choice of the individual with a disability. Commenters stated that giving primary consideration to the choice of aid or service requested by an individual with a disability helps to ensure effective communication and equal opportunity in the healthcare setting. Commenters commended HHS for holding all recipients of Federal financial assistance from HHS to the higher ADA Title II standards.

Response: Access to care continues to be a critical concern for the Department, and access to care clearly requires effective communication. The Department does not believe this final rule will impede individuals' access to care, but that instead it will assist individuals in understanding a covered entity's legal obligations and their own rights under Section 1557. In addition, the rule will assist the Department in complying with the mandates of Congress and further substantive compliance. Finally, because this final rule will lift unnecessary regulatory burdens on providers, the Department hopes that it will increase access to care, including in underserved and rural communities.

Comment: Commenters noted that the current regulation's language tracks the statutory text of Title I and Title III of the ADA and the regulatory language of Title II of the ADA, all of which protect against discrimination based on association or relationship with a person with a disability. They said that the proposed rule's elimination of the 2016 Rule's prohibition on associational discrimination will therefore create bewilderment concerning providers' responsibilities and individuals' rights. Commenters argued that deleting the language will create uncertainty and confusion regarding the responsibilities of providers and the rights of persons who experience discrimination, and inconsistencies with other regulatory requirements that entities are subject to, including the ADA and Section 504.

Response: As stated above, protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under the incorporated civil rights statutes and their implementing regulations. The Department notes that courts have often relied on ADA statutory provisions in their handling of Section 504 claims.[288]

[287] *Lau* v. *Nichols,* 414 U.S. 563 (1974).

[288] *See* Memorandum on Coordination of Federal Agencies' Implementation of Title II of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, Acting Assistant Attorney General (April 24, 2018); *see, e.g., Theriault* v. *Flynn,* 162 F.3d 46, 48 n.3 (1st Cir. 1998); *Henrietta D.* v. *Bloomberg,* 331 F.3d 261,272 (2d Cir. 2003); *Helen L.* v. *DiDario,* 46 F.3d 325, 330 n.7 (3rd Cir. 1995); *Baird ex rel. Baird* v. *Rose,* 192 F.3d 462, 468 (4th Cir. 1999); *Delano-Pyle* v. *Victoria Cty., Tex.,* Continued

Comment: Several commenters objected that the definition of auxiliary aids and services at proposed § 92.102(b)(1) excludes the term ''Qualified'' before ''Interpreters'' in subsection (i) and before ''Readers'' in subsection (ii), despite being part of the ADA definition at 28 CFR 35.104. Some Commenters strongly encouraged the Department to incorporate the ADA definition of ''Qualified Reader'' as follows: ''Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.'' [289]

Response: As stated above regarding § 92.101(a), this final rule eliminates the term ''qualified'' from the 2016 Rule only where it was redundant and clearly implied by the context. In this case, subsection (b)(2) clearly lists the mandatory qualifications for interpreters required under subsection (b)(1), and it adopts that list from the ADA definition at 28 CFR 35.104 and § 36.303(f). It would therefore be redundant to describe those interpreters in subsection (b)(1) as ''qualified.'' No definition of ''Qualified Reader'' appears in the 2016 Rule, so the Department is making no change in that regard. But the Department interprets this subsection naturally as requiring qualifications for readers that are similar to the expressly stated qualifications for interpreters.

Comment: Commenters argued that although the proposed rule claims to incorporate the definition of auxiliary aids and services from the regulations implementing Title II of the ADA, the rule as proposed changes the definition of auxiliary aids and services, omitting ''acquisition or modification of equipment and devices; and other similar services and actions'' from the list of examples of aids and services. Commenters noted that this proposed change will confuse providers and people with disabilities and will lead both groups to assume the list in the proposed rule is exhaustive. Commenters opposed these deletions and requested that the Department retain the definition of auxiliary aids and services from the 2016 Rule.

Response: The Department's definition of auxiliary aids and services is consistent with, even if not identical to, that of the ADA. The Department does not deem it necessary to incorporate all of the ADA's examples, as neither the ADA's list nor this final rule's list claims to be exhaustive.

Comment: Some commenters expressed concern regarding the narrowing of the ''free of charge'' and ''timely manner'' provision at proposed § 92.102(b)(2). Commenters noted that the 2016 Rule's language is consistent with existing ADA Title II regulations, which provide that covered entities may not place a surcharge on a particular individual or group of individuals with a disability to cover the costs of the provision of auxiliary aids or program accessibility. Commenters asserted that the proposed § 92.102(b)(2) significantly narrows this provision by stating that ''interpreting service'' shall be provided to individuals free of charge and in a timely manner. These commenters strongly opposed this change and encourage the Department to replace the words ''interpreting service'' with ''auxiliary aids and services'' to be consistent with the ADA and to prevent unnecessary confusion over the requirement.

Response: Like § 92.202 of the 2016 Rule, which it replaces, § 92.102 of this final rule continues to incorporate the ADA Title II regulations at 28 CFR 35.160–164. The new section also includes new language on the qualifications for interpreters, which is where the term ''free of charge'' now appears; the term did not appear in § 92.202 of the 2016 Rule. To the extent that auxiliary aids must be provided free of charge under the 2016 Rule, they must still be provided free of charge under this final rule.

Comment: One commenter asked that the phrase ''in a timely manner'' as used in Section 92.102(b)(2) of the proposed rule be clarified with clear guidance as to what can and cannot be considered ''in a timely manner.''

Response: Application of the term ''in a timely manner'' requires a nuanced analysis that is fact-dependent. Its meaning can be understood from the long history of enforcement of Section 504 and the ADA in the courts and administratively.

Comment: Some commenters supported an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees, stating that it would help alleviate financial and administrative burden for smaller physician group practices that may already have limited resources. Others said that in some areas of the country, especially in small and rural communities, such an exemption could effectively bar access to many providers. Commenters said that any such exemption would be inconsistent with the standard present in Title II [290] and Title III [291] of the ADA, which require the same businesses to provide auxiliary aids and services to individuals with disabilities where necessary to ensure effective communication, regardless of the number of employees. They said that the existence of two competing regulatory standards will confuse small covered entities as to which standard they should follow. Several commenters noted that although a small economic burden may be placed on small businesses that have to comply with this requirement, there are programs that provide tax benefits and funding for the provision of reasonable accommodations, significantly reducing the burden placed on these entities.[292] Some commenters noted that because Titles II and III of the ADA already provide for sufficient mechanisms for providers to request exemptions based on a fundamental alteration in the nature of goods and services provided and undue burden, no additional exemption is needed through Section 1557.

Response: The Department believes that in the interest of uniformity and consistent administration of the law, all employers that receive Federal financial assistance from HHS, regardless of their size, should be held to the auxiliary aids and services requirement. The Department recognizes the importance of individuals being able to effectively communicate with their healthcare providers and is aware that the inability to effectively communicate can have significant adverse effects on individuals' access to effective healthcare. The Department's decision to require all entities, regardless of size, to provide auxiliary aids and services is consistent with OCR's policy for almost two decades,[293] so covered entities will

302 F.3d 567, 574 (5th Cir. 2002); *McPherson* v. *Michigan High School Athletic Ass 'n, Inc.,* 119 F.3d 453, 459–60 (6th Cir. 1997); *Gorman* v. *Bartch,* 152 F.3d 907, 912 (8th Cir. 1998); *Zukle* v. *Regents of Univ. of Cal.,* 166 F.3d 1041, 1045 n.11 (9th Cir. 1999); *Cohan ex rel. Bass* v. *N.M. Dept. of Health,* 646 F.3d 717, 725–26 (10th Cir. 2011); *Bircoll* v. *Miami-Dade Cty.,* 480 F.3d 1072, 1088 n.21 (11th Cir. 2007).

[289] 28 CFR 35.104.

[290] 28 CFR 35.104.

[291] *See* 42 U.S.C. 12182(b)(A)(iii) (under Title III, privately operated public accommodations regardless of their size are obligated to provide appropriate auxiliary aids and services, when necessary to ensure effective communication with individuals with disabilities, unless the entity can demonstrate that taking such steps would fundamentally alter the nature of their programs, services or activities, or would result in undue financial and administrative burdens).

[292] Commenters cited U.S. Department of Justice American with Disabilities Act Update: A Primer for Small Business. (2010). Retrieved from *https://www.ada.gov/regs2010/smallbusiness/smallbusprimer2010.htm;* Internal Revenue Service. (n.d.); Form 8826, Disabled Access Credit. Retrieved from *https://www.irs.gov/forms-pubs/about-form-8826.*

[293] *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).

be familiar with the obligations being imposed. Title II and Title III of the ADA already require public and private healthcare entities to provide auxiliary aids and services regardless of the number of employees. Both Titles state that an entity is not required to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, and § 92.102 incorporates both of those limitations through its incorporation of the ADA Title II regulations at 28 CFR 35.160–164. Therefore, the Department finds it appropriate not to adopt an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees.

Comment: Commenters said that the ''primary consideration'' standard has evolved such that patients will demand that a particular translator or interpreter be used, regardless of the expense. These commenters argued that when patients demand use of a certain company or specific commercial service, this creates additional unnecessary costs for the covered entity. One commenter stated that Title III of the ADA should be the standard that applies to private businesses covered by Section 1557 regarding effective communication for individuals with disabilities. The commenter asserted that the Title II primary consideration standard is not appropriate for use in a clinical setting and that treating clinicians or the entities themselves are in the best position to determine the types of services necessary to address the communication needs of their patients. The commenter argued that applying Title II standards to private entities has created significant confusion for medical group practices accustomed to following longstanding Title III rules.

Response: Since the 2015 NPRM, the Department has held that it is appropriate, as a condition of receipt of Federal financial assistance from HHS, to hold all recipients to the higher 2010 ADA Title II standards regarding effective communication with individuals with disabilities.[294] The Department does not consider the commenters' concerns to be a sufficient reason to change this policy. Section 92.102 of this final rule seeks to avoid confusion by providing covered entities with clear, specific guidance to help them understand their rights and responsibilities regarding effective communication with individuals with disabilities. As mentioned above, it also incorporates the ''undue burden'' and ''fundamental alteration'' limitations of ADA Title II, in order to avoid excessively burdening covered entities.

(3) Accessibility Standards for Buildings and Facilities (45 CFR 92.103)

The Department proposed at § 92.103(a) to retain the 2016 Rule's requirement that new construction or alteration of buildings or facilities subject to Section 1557 must comply with the 2010 ADA Standards for Accessible Design by January 18, 2018, and to retain the 2016 Rule's allowance of departures from the 2010 ADA standards where other methods are permitted that provide substantially equivalent or greater access to and usability of the building. 84 FR at 27867. The Department proposed at § 92.103(b) to create 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 Uniform Federal Accessibility Standards (''UFAS''), the 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. Finally, the Department proposed at 92.103(c) to identify the three applicable building and facility detailed technical accessibility standards by cross-reference to their underlying regulations, instead of listing them in a separate definitions section.

Upon further consideration of this language and the public comments, the Department observed a potential ambiguity in § 92.203 of the 2016 Rule. The rule distinguished between construction or alteration commenced ''on or after July 18, 2016'' in the first sentence of § 92.203(a), those commenced ''on or before July 18, 2016'' in the first sentence of § 92.203(b), and those commenced ''before July 18, 2016'' in the last sentence of § 92.203(b). This potentially left it unclear how the rule would apply to construction or alteration commenced on July 18, 2016. To avoid confusion, the Department is finalizing § 92.103 with a technical change, by deleting the phrase ''on or'' from the first sentence of § 92.103(a), and adding ''on or'' before the word ''before'' in the last sentence of § 92.103(b). This resolves the ambiguity while providing leeway to activities commenced on July 18, 2016 where it was not clear how the 2016 Rule applied.

Comment: Commenters supported the proposal to continue to apply the 2010 ADA Standards' definition of ''public building or facility'' to all entities covered under Section 1557, by retaining the provisions of 45 CFR 92.203 (redesignated § 92.103) regarding accessibility standards for buildings and facilities. Commenters opposed any type of additional exemption from the requirements concerning multistory building elevators [295] and Text Telephone (TTY) requirements.[296] Some commenters strongly opposed the proposed rule's incorporation of the private entity TTY standard from the 2010 ADA Standards, and requested the retention of the existing TTY ratios, and the adoption of stringent Real-Time Text (RTT) ratios. Others noted that lack of accessible medical equipment presents barriers to effective healthcare for people with impaired mobility or strength and other disabilities, and they requested that the Department require healthcare facilities to follow the 2017 Architectural and Transportation Barriers Compliance Board (U.S. Access Board) Standards for Accessible Medical Diagnostic Equipment.[297]

Response: The Department believes that, because the great majority of entities covered by the 2016 Rule have already been subject to the 2010 ADA Standards, an approach that emphasizes uniform application of the 2010 Standards will promote conformity with pre-existing civil rights statutes while enabling greater consistency among implementing agencies. Any significant reevaluation of those standards or adoption of new standards is beyond the scope of this regulation. In the case of adopting new standards, the Department also declines to make such a significant regulatory change without the benefit of notice and public comment.

(4) Accessibility of Information and Communication Technology (45 CFR 92.104)

The Department proposed to retain the 2016 Rule's provisions on accessibility of information and communication technology for individuals with disabilities. 84 FR at 27867. The Department also proposed at 92.104(c) to update the 2016 Rule's

[294] 80 FR 54186.

[295] *See* 42 U.S.C. 12101 *et seq.* Exception 1 of section 206.2.3 of the 2010 ADA standards exempts multistory buildings besides the professional office of a healthcare provider owned by private entities from the requirement to provide an elevator to facilitate an accessible route throughout the building. This exemption does not apply to public entities.

[296] 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).

[297] *See* Information and Communication Technology (ICT) Standards and Guidelines, 82 FR 5790 (Jan. 18, 2017) (final rule); 83 FR 2912 (Jan. 22, 2018) (technical edits).

outdated term ''electronic and information technology'' with the term ''information and communication technology,'' as defined in the U.S. Access Board regulations. 84 FR at 27871.

Comment: Commenters expressed concern with the Department's proposed change to the definition of ''information and communication technology'' (ICT), in proposed § 92.104(c). Commenters noted that the critical phrase ''but are not limited to'' has been removed from the definition the Department claims to have incorporated from the U.S. Access Board's definition for ICT.[298] The commenters argue that due to the difficulty in predicting what technologies will be in place moving forward, it is important to maintain flexibility and ensure that the regulation keep pace with emerging technologies.

Response: The list of auxiliary aids was not intended as an all-inclusive or exhaustive catalogue of possible or available auxiliary aids or services—nor could it possibly be, given the new devices that will become available with emerging technology. The Department omitted the phrase ''but are not limited to'' merely in order to avoid unnecessary legal jargon. The plain meaning of ''include'' already encompasses ''but are not limited to,'' as it signifies that the listed items are only parts of a larger whole.

Comment: One commenter requested that the Department require recipients of Federal financial assistance to ensure that health programs or activities provided through their websites comply with the requirements of Title III, rather than Title II, of the ADA, if the recipient is otherwise covered by Title III. The commenter argued that the burden placed on small practices by having to comply with both Title II and Title III would likely outweigh any benefit to individuals who require accessible technology.

Response: The Department believes that this comment understates the benefit of the Title II standards to individuals who require accessible technology. Effective communication is a critical component for individuals to be able to access and receive healthcare, and this includes being able to access covered entities' websites. The Department believes that in the interest of uniformity of access for individuals with disabilities, all entities that receive Federal financial assistance from HHS should be held to the higher information and communication technology standards of Title II. The ADA does not exempt small providers from this requirement, although § 92.104 does incorporate the ADA's ''undue financial and administrative burden'' and ''fundamental alteration'' exemptions in order to protect covered entities from excessive burdens.

Comment: Some commenters stated that the Department should cross-reference Section 508 in its proposed § 92.104. The commenters noted that although the proposed rule tracks the concepts of the Section 508 regulations, it does not include the appropriate cross-reference, which will cause confusion if and when the Section 508 regulations are updated.

Response: If and when Section 508 regulations are updated, the Department will evaluate whether or not to update § 92.104 accordingly. Because this final rule does not incorporate Section 508 regulations but merely tracks them, the Department believes that a cross reference could cause unnecessary confusion if and when Section 508 regulations are updated or changed.

(5) Requirement To Make Reasonable Modifications (45 CFR 92.105)

The Department proposed at § 92.105 to retain the 2016 Rule's requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that the modification would fundamentally alter the health program or activity. 84 FR at 27868. The Department sought comment on whether to include an exemption for ''undue hardship.'' *Id.*

Comment: Commenters strongly opposed an exemption for undue hardship in regard to the requirement that covered entities 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. Commenters pointed out that the current regulations track Title II of the ADA. Commenters stated that Title III does not absolve a covered entity from providing all forms of auxiliary aids if providing a particular auxiliary aid would result in undue burden, and that a provider has an obligation to find an alternative auxiliary aid in such cases. Commenters noted that because Title II and III of the ADA already provide mechanisms for providers to request exemptions based on an undue burden, no additional exemption is needed. Commenters stated that the substitute language proposed is from regulations related to employment and ill-fitting and inappropriate in a healthcare context. Commenters requested that if an exemption for undue hardship is provided, it should mirror the undue burden provision of the ADA, to ensure the two Federal laws are in sync and do not conflict with one another and lead to confusion.

Response: The Department agrees with commenters who ask that the regulations continue tracking Title II of the ADA, whose requirement for reasonable modifications includes a fundamental alteration exemption but no undue hardship exemption. The Department believes that this position helps promote continued consistency with pre-existing civil rights statutes. The reasonable modification analysis already applies to many entities subject to Section 1557 and is well-defined by regulation and decades of case law. Continuing to apply the ''reasonable modification'' analysis to Section 1557 promotes consistency with pre-existing civil rights law and is consistent with the U.S. Supreme Court's decision interpreting Section 504 in *Alexander* v. *Choate,* 469 U.S. 287 (1985), Title II of the ADA, and OCR's longstanding interpretation of Section 504.

Comment: Commenters objected to substituting the Title II reasonable modification language with language stating that covered entities ''shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified'' individual with a disability. Further, a commenter argued that use of the term ''known,'' outside the employment context, would suggest an overly narrow interpretation of the scope of Section 1557 and introduce an unnecessarily burdensome and intrusive process into the healthcare context. Commenters expressed concern that importing the ''known physical or mental limitation'' language would suggest to covered entities that their obligations are limited, and would create an undue focus on the measures that entities must take in response to requests for modifications.

Response: The Department shares the concern that introduction of the phrase ''known physical or mental limitations'' may cause covered entities to introduce

[298] *See* 36 CFR app. A § 1194 (2011) (defining ICT as ''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 but are not limited to: Computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and electronic documents.'').

exceedingly burdensome and intrusive processes into the healthcare context. In contrast, the concept of reasonable modification taken from Title II has long applied to a wide range of entities covered by Section 1557, making such entities familiar with the requirements imposed, and is well-defined by regulation and decades of case law. The Department believes that continuing to apply the reasonable modification analysis to Section 1557 will help promote consistency with pre-existing civil rights statutes.

Comment: Several commenters noted that the citation for the proposed reasonable modification language the Department claims conforms to the Department of Justice's Section 504 coordinating regulations is to a non-existent portion of the Code of Federal Regulations. These commenters argue that these incorrect citations make it impossible for the public to analyze the context or case law of the proposed imported language and that such uncertainty makes it impossible for the public to reliably know what the Department is proposing.

Response: The Department thanks these commenters for bringing this citing error to its attention. For clarity, the Department notes that it intended to cite to 28 CFR 42.511, not § 92.205.[299] But for the reasons stated above, the Department has determined that it should retain the current Title II reasonable modification language.

Comment: Some commenters recommended that the rule include the addition of examples of programmatic modifications that are often needed by those with disabilities, such as the modification of wait times, office hours, and other business practices that can make accessibility to healthcare for people with disabilities difficult.

Response: The Department declines to enshrine a list of examples of ''programmatic modifications'' needed by those with disabilities. Because this final rule applies to a diverse range of covered entities, codifying examples would not provide meaningful guidance to the full spectrum of regulated covered entities. The Department believes that each covered entity ought to determine for itself which programmatic modifications with respect to its health programs and activities should be undertaken to avoid discrimination on the basis of disability, subject to enforcement by OCR in case of a complaint.

Comment: Commenters found inappropriate the Department's requesting comment on whether it has struck the appropriate balance in proposed §§ 92.102 through 92.105 with respect to Section 504 rights and obligations imposed on the regulated community, as such a balancing exercise is not called for by the statute and inserts inappropriate regulatory subtlety.

Response: In any rulemaking, addressing obstacles that impede individuals from exercising their rights should be balanced against potentially unnecessary obligations that may be imposed on the regulated community. Agencies engage in this type of balancing in order to ensure that the interests and issues of both individuals and the regulated community are fairly considered during the rulemaking process, helping to minimize the burden associated with Federal regulations.

Comment: A commenter said that in order to promote clarity and affirm that VRI quality standards apply in any remote interpreting situation that may arise for a person with a disability, § 92.101 of the proposed rule ought to cross-reference the VRI quality standards in § 92.102.

Response: Section 92.102 covers individuals with disabilities. § 92.101 covers individuals with LEP status, which is not a disability. Individuals with disabilities have different needs than LEP individuals, and the current regulatory text reflects that difference. If an LEP individual happens also to have a disability, then the VRI quality standards of § 92.102 will apply to him/her.

(6) Summary of Regulatory Changes

The Department finalizes the proposed sections § 92.101 through 92.105 without change, except that technical changes are made to add the word ''or'' at the end of § 92.101(b)(4)(ii)(A), to delete the phrase ''on or'' from the first sentence of § 92.103(a), and to add the phrase ''on or'' before the word ''before'' in the last sentence of § 92.103(b).

D. Title IX Regulations

The Department proposed to conform its Title IX regulations to current statutory provisions.

(1) Nomenclature, Rules of Appearance, Effective Date Modifications to Rules at 45 CFR 86.31 and 86.71

The Department proposed to make a nomenclature change to the Title IX regulation by replacing ''United States Commissioner of Education'' with the official's current title, ''Secretary of Education.'' [300] The Department also proposed to update the Title IX regulation's statutory citations to include the full current text of Title IX as amended by the CRRA.

The Department also proposed to repeal a prohibition on discrimination on the basis of ''rules of appearance'' in 45 CFR 86.31. The Department further proposed to update the enforcement section in the Department's Title IX regulation at 45 CFR 86.71, which currently discusses only enforcement procedures for the interim period before the issuance of the consolidated Title IX regulation. This final rule applies language from the Title IX regulation, which incorporates Title VI procedures.

Comment: The Department received comments indicating that the rules of appearance prohibition is well supported by Title IX and that HHS provides no basis for removing the prohibition.

Response: This final rule's NPRM explained that 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.'' [301] The phrase ''rules of appearance'' does not appear in Title IX and was never defined in any agency's Title IX regulations. Consequently, the Department believes 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. Because this language is not in the current regulations of any other agencies, this final rule limits the potential for conflicting and inequitable Federal agency enforcement of Title IX with respect to ''rules of appearance.''

(2) Abortion Neutrality of 20 U.S.C. 1688 in 45 CFR 86.2 and 86.18

The Department also proposed to modify its Title IX regulations, at 45 CFR 86.18, to reflect the statutory text Congress enacted in Title IX. This text includes what some commenters referred to as the Danforth Amendment, 20 U.S.C. 1688, which states that Title IX is not to 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; to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use

[299] *See* 84 FR 27868 (citing to 28 CFR 92.205).

[300] *See* 45 CFR 86.2(n).

[301] *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).

of facilities, related to an abortion; or 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.[302] The Department also proposed to add a provision, similar to the provision of the Section 1557 regulation discussed above under ''relation to other laws,'' ensuring that its Title IX regulation would be construed consistently with various religious freedom and conscience statutes, including the explicit religious exemptions in the text of Title IX itself.

Comment: One commenter stated that adding Title IX's abortion neutrality language in the Department's Title IX regulations would be a violation of the plain language of the definition of sex discrimination in the regulations, which includes termination of pregnancy. Others noted that discrimination based on termination of pregnancy has been recognized by courts as sex discrimination and therefore argued that the proposed rule is contrary to civil rights laws and constitutional principles. Some noted that Title IX itself expressly does not permit penalties based on a woman's prior termination of pregnancy.

Others, however, supported the incorporation of Title IX's religious exemptions and other Federal conscience statutory protections, arguing that they are consistent with abortion neutrality. Still others stated that discrimination on the basis of sex should not include termination of pregnancy at all, under existing law and the statutory text of Section 1557 and Title IX. Some submitted legislative history from Title IX (Senate Committee Report 100–64) to show that Congress intended to allow for abortion exemptions and exclusion of health insurance coverage for abortion services, and that Congress did not intend to require all hospitals to provide abortion services to the general public.[303] But other commenters were critical of using legislative history to interpret a statute.

Response: This final rule does not remove the language from the Department's Title IX regulations that prohibits certain forms of discrimination on the basis of ''termination of pregnancy.'' [304] However, as stated above in the section on discrimination on the basis of sex (subsection on ''termination of pregnancy''), the Title IX regulations are governed by the text of the Title IX statute and cannot 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'' (20 U.S.C. 1688). This final rule adds language to the Title IX regulations in order to make this clear. Although some commenters cite legislative history, the Department interprets the statutory text as written. Regardless, the Department does not believe there is tension between the legislative history and the text.

By adding the abortion neutrality language to the Title IX regulations, and stating in the Section 1557 regulation that it will be applied consistent with Title IX (including that language), this final rule ensures compliance with the rationale in *Franciscan Alliance,* where the Court rightly held that the Department's regulations forbidding discrimination on the basis of sex must be construed in light of the underlying text of Title IX, including abortion neutrality.

Comment: Commenters stated that religious exemptions would make it harder to find healthcare in low provider areas, and that religious refusals also harm people who live in rural areas and must travel for an abortion. However, other commenters stated that this inclusion of various Federal conscience statutes and appropriations riders would ensure that healthcare providers who have conscience objections to abortion will feel welcome within the healthcare profession and will ease retention of healthcare providers already in the field.

Some specifically stated their support for the Department's inclusion of the First Amendment, and for Department guidance that the proposed rule be construed consistent with religious liberty and free speech protections, to clarify that the interpretation, application, and enforcement of the proposed rule will be consistent with religious liberty. Other commenters stated that referring to the First Amendment rightly addresses the recent Supreme Court ruling in *NIFLA* v. *Becerra.*[305] Commenters were concerned that the 2016 Rule would require a faith-based hospital to inform a patient about terminating her pregnancy in direct contravention of sincerely-held religious beliefs. This would be in conflict with *NIFLA,* where the Supreme Court held that such a mandate ''imposes an unduly burdensome disclosure requirement that will chill [] protected speech.'' [306]

Response: The Department agrees that this final rule should be construed consistent with the First Amendment, conscience statutes, and all relevant statutes and appropriations riders relating to abortion, to the extent they remain in effect or applicable. Agency regulations are subject to the requirements of the First Amendment in any case, and the Department considers it appropriate to say so explicitly here. All the other laws referenced establish Congressionally required parameters that may apply to the Department's interpretation, implementation, and enforcement of Title IX and of this final rule.[307] Commenters' policy objections to these statutory constraints are not a sufficient reason for the Department not to finalize this provision of the rule, which will ensure compliance with statutory requirements.

(3) Summary of Regulatory Changes

For the reasons described herein and having considered the comments received, the Department finalizes changes to 45 CFR 86.2, 86.18, 86.31, and 86.71 without change.

E. Conforming Amendments to CMS Regulations

The Department proposed to make conforming amendments to ten regulations of CMS that prohibited discrimination on the basis of gender identity and/or sexual orientation in the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of QHPs under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the PACE program. These conforming changes were proposed, among other

[302] *See* Public Law 100–259, 102 Stat. 28, sec. 8 (Mar. 22, 1988) (codified at 20 U.S.C. 1688).

[303] *See* Senate Committee Report 100–64 (''This bill does not expand abortion rights. Religiously-controlled organizations will continue to be able to apply for, and receive, an exemption from Title IX requirements where compliance with those requirements would violate their religious tenets. For example, a religiously controlled university that wished to exclude insurance coverage of abortions from an otherwise comprehensive student health insurance policy, could seek a religious exemption. . . . Title IX covers only students and employees, and does not reach the public at large. Therefore, claims that the bill would require hospitals to provide abortion services to the general public are false.'').

[304] *See* 45 CFR § 86.21(c)(3), 86.40(b)(1), 86.40(b)(4), 86.40(b)(5), 86.51(b)(2), 86.51(b)(6), 86.57(b), 86.57(c), 86.57(d).

[305] *Natl. Inst. of Fam. and Life Advocates* v. *Becerra,* 138 S. Ct. 2361 (2018).

[306] *Id.* at 2378.

[307] To the extent the relevant provisions are found in an appropriations rider, they apply to the Department's interpretation, implementation, and enforcement of Title IX every year that they are enacted.

reasons, to ensure uniformity across the Department with respect to regulations that cover many of the same entities.

(1) Generally

Comment: Several commenters contended that the proposed rule exceeds the authority of the Director of OCR by attempting to remove references to gender identity and sexual orientation from all HHS healthcare regulations, including those issued by other HHS agencies unrelated to Section 1557, although the rule purported to be promulgated by authority from Section 1557 and other sections within the ACA. Commenters stated that the nondiscrimination protections proposed to be eliminated from CMS regulations are unrelated to Section 1557 and its regulation, and that this elimination was proposed without sufficient legal, policy, or cost-benefit analyses as well as without knowledge of their potential impacts on various CMS programs and on LGBT patients, who (commenters said) may be discriminated against if these amendments are finalized. Also, commenters contend the conforming amendments, if implemented, would affect a wide range of healthcare programs, including private insurance and education programs. Some said they were unaware of any instances in which inclusion of sexual orientation as a basis for nondiscrimination in these CMS rules had been challenged or opposed. Others said that it was arbitrary to single out sexual orientation and gender identity for elimination, since some of the CMS regulations being amended also protect other characteristics not expressly enumerated by statute.

Response: Both the proposed rule and this final rule are promulgated by the Secretary of Health and Human Services, who has jurisdiction over all Department regulations, including those falling under the jurisdiction of CMS. Moreover, each of the programs, activities, or entities in the proposed conforming amendments falls within the scope of Section 1557 as entities established under Title I of the ACA (for example, Exchanges [308]), entities administered under Title I of the ACA (for example, QHPs [309]) or health programs or activities receiving Federal financial assistance from the Department, including contracts of insurance.[310] The ACA and certain Federal statutes identifying other protected categories provide the bases for the nondiscrimination clauses in health programs and activities funded or administered by HHS.[311]

The Department has reviewed the legal authorities underlying and cited in the nondiscrimination provisions of these CMS regulations and the explanations set forth in those rules. Some of them relied on or referenced Section 1557, some relied on different statutory provisions, and some are cross-referenced in the 2016 Rule. None of the statutory authorities underlying the CMS rules amended here explicitly references sexual orientation or gender identity. To the extent some of those regulations were promulgated based on broad authority to issue regulations,[312] inclusion of nondiscrimination criteria that are not explicitly set forth in other applicable civil rights statutes may not necessarily exceed the Department's statutory authority. Nevertheless, the Department deems it appropriate to pursue a more uniform practice concerning nondiscrimination categories across programs and activities to which Section 1557 applies, and to do so consistent with the government's position concerning discrimination on the basis of sex.

In addition, for several of the CMS final rules, their corresponding proposed rules had not mentioned adding sexual orientation and gender identity as nondiscrimination categories.[313] Although some of those proposed rules also did not mention adding other common nondiscrimination categories, the Department now views the addition of sexual orientation and gender identity as nondiscrimination categories as having presented different legal and policy concerns from other categories. Notably, these nondiscrimination categories are not required by applicable law, appear in only a handful of federal antidiscrimination statutes, and have been the subject of extensive litigation, controversy, and confusion generally. Thus, the Department believes the addition of sexual orientation and gender identity as nondiscrimination categories in its regulations should have been submitted for public comment and, notwithstanding the lack of legal challenge to these CMS regulations on this basis, proposes conforming amendments for purposes of clarity, consistency, and uniformity.

Therefore, the Department deems it appropriate to finalize the proposed conforming amendments to these CMS regulations without change (with the exception of a technical correction described below), in order to create a more uniform practice concerning nondiscrimination on the basis of sex among HHS programs to which Section 1557 applies, and to avoid the possibility that there was insufficient statutory authority to impose gender identity or sexual orientation nondiscrimination prohibitions through those regulations.

The Department is unaware of any data that would make cost-benefit analyses for these specific changes possible, and notes that the insertion of sexual orientation and gender identity language (repealed by these amendments) had already been implemented without any cost-benefit analyses. These provisions are eliminated for reasons parallel to those put forth here and in the proposed rule with respect to proper statutory construction, legal authority, and the Department's policy goals.

Comment: Some commenters supported proposals to remove the provisions prohibiting discrimination on the basis of sexual orientation specifically from regulations encompassed by the conforming amendments, in order to reflect current law and current regulatory policy. They reiterated the 2016 Rule's statement that there is no settled statutory law or court-settled law that discrimination on the basis of sexual orientation is legally included within the reach of Title IX.

Response: For the reasons explained above, the Department agrees with the 2016 Rule's decision not to include an explicit prohibition on sexual orientation discrimination. Similarly, the Department concludes it is appropriate to remove such language through these conforming amendments.

(2) Delivery of Medicaid Services (42 CFR 438.3(d)(4), 438.206(c)(2), 440.262)

The Department proposed conforming amendments to multiple provisions in Title 42 of the Code of Federal Regulations that apply to delivery of

[308] *See* Public Law 111–148, tit. I, subtit. D, Part II (Consumer Choices and Insurance Competition Through Health Benefit Exchanges).

[309] *See* Public Law 111–148, tit. I, subtit. D, Part I (Establishment of Qualified Health Plans).

[310] These include Medicare Advantage (Medicare Part C) plans, Medicare Part D plans, Medicaid Managed Care Organizations (MCOs), Medicaid Prepaid Inpatient Health Plans, (PIHPs), Medicaid Prepaid Ambulatory Health Plans (PAHPs), Medicaid Primary Care Case Managers (PCCMs), Primary Care Case Management Entities (PCCM-Es) and Programs for All-inclusive Care for the Elderly serving Medicare and Medicaid beneficiaries (PACE).

[311] *See* 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(a)(3), 460.112(a).

[312] *See, e.g.,* ACA Section 1321 (42 U.S.C. 18041(a)) (authorizing the Secretary to ''issue regulations setting standards . . . with respect to . . . the establishment and operation of Exchanges . . . the offering of qualified health plans through such Exchanges . . . and . . . such other requirements as the Secretary determines appropriate'').

[313] *See, e.g.,* 78 FR 13406 (Feb. 27, 2013) (final rule) and 77 FR 70584, 70585 (Nov. 26, 2012) (NPRM).

Medicaid services found in § 438.3(d)(4) as applied to MCOs, PIHPs, PAHPs, PCCMs or PCCM entities, § 438.206(c)(2) by MCOs, PIHPs, and PAHPs participating in State efforts, and § 440.262 by the States themselves.

Three of the provisions applied to Medicaid managed care. The Department proposed on June 1, 2015, and then finalized on May 6, 2016, a regulation with several nondiscrimination provisions applicable to fee-for-service medical assistance under Medicaid. 80 FR 31098 (June 1, 2015) (Medicaid NPRM); 81 FR 27895 (May 6, 2016) (Medicaid final rule). The Department prohibited discrimination on the basis of ''sexual orientation and ''gender identity'' by MCOs, PIHPs, PAHPs, PCCMs, and PCCM-Es. 42 CFR 438.3(d)(4). And it required that certain of these entities promote access and/or delivery of services ''in a culturally competent manner to all enrollees . . . regardless of gender, sexual orientation or gender identity.'' 42 CFR§ 438.206(c)(2).

In promulgating these regulations, the Department relied on a statute granting general rulemaking authority to the Secretary of HHS to make and publish rules and regulations as may be necessary to efficiently administer Medicare and Medicaid. Section 1102 of the Social Security Act, 42 U.S.C. 1302(a). It also cited provisions of the Social Security Act that require Medicaid State plans for medical assistance to ''provide . . . such methods of administration . . . as are found by the Secretary to be necessary for the proper and efficient operation of the plan.'' Section 1902(a)(4) of the Social Security Act (42 U.S.C. 1396a(a)). And it cited Section 1902(a)(19) of the Social Security Act to justify additional methods of administration and new protected categories necessary for the proper operation of a State plan, for best interest of the beneficiaries, and for cultural competency. 81 FR 27895 (Medicaid final rule). None of these authorities prohibits discrimination on the basis of gender identity or sexual orientation.

In reviewing § 440.262, the Department became aware that in proposing a conforming amendment to the first sentence, the proposed rule is worded to delete the second sentence of that section, which reads ''These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.'' The Department's intent was to make a conforming amendment to the first sentence of that section, but not to delete the second sentence. Therefore, the Department finalizes the conforming amendment to the first sentence of § 440.262 without change, but makes a technical correction by finalizing the section to retain the second sentence of that section. In other words, the Department is finalizing the change to the first sentence of § 440.262, but is not finalizing the deletion of the second sentence. In addition, the Department corrects the grammar of the second sentence, by changing the word ''meet'' to ''meets.'' Medicare's PACE Program Employees and Organizations (42 CFR 460.98(b)(3), 460.112(a)).

The Department proposed conforming amendments to two provisions that apply to PACE, a health program receiving HHS Federal financial assistance that is therefore subject to Section 1557.

In 2006, the Department promulgated a regulation administering PACE that prohibited discrimination on the basis of sexual orientation. 71 FR 71244 (Dec. 8, 2006) (PACE final rule). Sexual orientation had not been identified as a protected category in the statute authorizing PACE. *See* Public Law 98–21, as amended (codified at 42 U.S.C. 1396u–4 *et seq.*).

In the PACE final rule, in response to a request from two commenters to ''broaden the list of categories under which the PACE Organization cannot discriminate to include sexual orientation,'' the Department agreed to amend 42 CFR 460.98(b)(3) to prohibit discrimination on the basis of sexual orientation for Medicare and Medicaid participants. The PACE proposed rule also prohibited discrimination on the basis of sexual orientation by employees and contractors of Medicare-participating PACE programs. 42 CFR 460.112(a) (providing that ''[e]ach 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, sexual orientation, mental or physical disability, or source of payment'').

Medicare Part A programs, including PACE, are subject to Title VI, Title IX, Section 504, and the Age Act. OCR has the authority to review recipient policies and procedures and certify that recipients of Federal financial assistance under Medicaid Part A comply with Title VI, Title IX, Section 504, and the Age Act, and their implementing regulations. CMS now directs applicants to an online attestation portal on the OCR website to assure compliance with those four civil rights statutes as well as with Section 1557.

In reviewing § 460.112(a), the Department became aware that in proposing a conforming amendment to the first two sentences, the proposed rule is worded to delete the remainder of the subsection. The Department's intent was to make a conforming amendment to the first two sentences of subsection (a), but not to delete its remainder. Therefore, the Department finalizes the conforming amendment to the first two sentences of § 460.112(a) without change, but as a matter of technical correction does not finalize the deletion of the remaining sentences, and instead finalizes subsection (a) to retain the remainder of that subsection.

Comment: Commenters expressed concern that PACE organizations would be allowed to discriminate against LGBTQ people under the proposed rule.

Response: The Department believes that everyone should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. None of the statutes authorizing the PACE regulations prohibits discrimination on the basis of gender identity or sexual orientation.

(3) General Standards for Exchanges, QHPs for Exchanges, and Health Plan Issuers (45 CFR 155.120(c)(ii)), 156.200(e))

In 2012, the Department added ''sexual orientation'' and ''gender identity'' into certain regulations for the administration of the ACA by States, the Exchanges, and QHP issuers. 77 FR 18469 (Mar. 27, 2012) (''Administration of Exchanges final rule''). The Department cited Section 1321 of the ACA as its authority to add new nondiscrimination requirements. 76 FR at 41873, 41897 (July 15, 2011) (''Administration of Exchanges proposed rule'').

Section 1321 is a general regulatory provision allowing HHS to regulate establishment, operation, and standards in Exchanges and for QHPs. It does not contain the words ''sexual orientation'' or ''gender identity,'' or specify that the authority to set standards includes the authority to specify classes protected from discriminatory conduct that are not otherwise specified in nondiscrimination statutes.[314] Sections 155.120(c)(ii) and 156.200(e) were both later referenced in the preamble to the 2016 Rule as nondiscrimination provisions that the 2016 Rule

[314] Section 1321(a) of the ACA provides that the Secretary of the Department of Health and Human Services ''shall, as soon as practicable after the date of enactment of this Act, issue regulations setting standards for meeting the requirements under this title, and the amendments made by this title, with respect to—(A) the establishment and operation of Exchanges (including SHOP Exchanges); (B) the offering of qualified health plans through such Exchanges . . .'' 42 U.S.C. 18041(a)(1)(A)–(B).

''complements.'' *See* 81 FR 31376, 31428 (May 18, 2016). The 2016 Rule also provided that the States, Exchanges, and issuers are ''obligated to comply with both sets of requirements.'' *Id.*

(4) Guaranteed Coverage (45 CFR 147.104(e))

In the February 27, 2013 edition of the **Federal Register**, the Department finalized a new regulation expanding the nondiscrimination provisions applicable to QHP issuers, including prohibitions on discrimination on the basis of gender identity and sexual orientation, citing Section 1321(a) of the ACA as the applicable statutory authority. 78 FR 13406 (Guaranteed Coverage final rule, codified at 45 CFR 147.104(e)). Nevertheless, the language in the final rule prohibiting discrimination on the basis of gender identity and sexual orientation was not in the proposed rule. *See* 77 FR 70584, 70613 (Nov. 26, 2012). It appears that the Department added this language in response to a commenter asking that HHS ''broaden[ ] [§ 147.104(e)] to apply to all forms of discrimination prohibited by the March 27, 2012 Exchange final rule and section 1557 of the Affordable Care Act, such as discrimination based on age, disability, race, ethnicity, gender, and sexual orientation, not just discrimination against individuals with significant or high cost healthcare needs.'' 78 FR at 13417.

As legal authority, the Department also relied on Section 2702 of the Public Health Service Act, as amended by the Affordable Care Act, Public Law 111–148 (Mar. 23, 2010), which only required that any ''individual or group market in a State must accept every employer and individual in the State that applies for such coverage.'' There was no explicit reference to categories of individuals protected by nondiscrimination laws.

The rule administered the ACA's guarantee of coverage in the group and individual health insurance markets. *See* 42 U.S.C. 300gg–1. The Department attached the sexual orientation and gender identity nondiscrimination provision as part of the requirement for issuers to accept every employer and individual in the State who applies for coverage, subject to a few exceptions. Section 300gg–1 does not specify nondiscrimination criteria, including sexual orientation or gender identity.

The rule applied not only to the health plan issuer but also to its ''officials, employees, agents and representatives.'' 45 CFR 147.104(e). It prohibited these covered entities from discriminating based on a variety of bases, including an individual's sex, sexual orientation, or gender identity. *Id.* In the Guaranteed Coverage final rule, the Department justified the 45 CFR 147.104(e) nondiscrimination provision on the ground that it ''ensures consistency with . . . the non-discrimination standards applicable to QHPs under § 156.200(e),'' to which sexual orientation and gender identity provisions had previously been added (as described above). 78 FR at 13426. The Guaranteed Coverage final rule was also referenced in the preamble to the 2016 Rule, which described it as both ''independent of'' and ''complement[ary]'' to Section 1557. 81 FR at 31428.[315]

The Department notes that this amendment to the Guaranteed Coverage final rule does not negate the rule's requirement that health insurance issuers offering group or individual coverage ''must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.'' 45 CFR 147.104(a). That requirement applies independent of the explicit nondiscrimination categories set forth in § 147.104(a).

(5) Enrollment in QHPs Through Exchanges by Agents or Brokers (45 CFR 155.220(j)(2)(i))

In the December 2, 2015 edition of the **Federal Register**, the Department proposed a rule that would prohibit agents or brokers from discriminating on the basis of sexual orientation and gender identity when assisting individuals and employers in applying for or enrolling in QHPs sold through a Federally-facilitated Exchange. 80 FR 75488. This proposed rule was adopted without change in March of the following year. 81 FR 12204 (Mar. 8, 2016) (codified at 45 CFR 155.220(j)(2)(i)). The final rule also stated that covered entities must comply with ''certain other Federal civil rights laws [that] impose non-discrimination requirements,'' such as Section 1557 of the ACA.[316] The final rule further directed issuers who seek certification of one or more QHPs to the OCR website for information about the Section 1557 NPRM.[317]

(6) Enrollment in QHPs and Exchanges by QHP Issuers (45 CFR 156.1230(b)(2))

In the September 6, 2016 edition of the **Federal Register**, the Department proposed a gender identity and sexual orientation nondiscrimination provision to rules governing marketing or conduct by issuers of individual market QHPs sold through the Federally-facilitated Exchanges in the direct enrollment of individuals in a manner that is considered to be through the Exchange. 81 FR 61456. The rule proposed that QHP issuers would be required to ''refrain from marketing or conduct that is misleading . . . coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.'' *Id.* The proposed language was finalized that December. 81 FR 94058 (Dec. 22, 2016) (codified at 45 CFR 156.1230(b)(3), since redesignated as 45 CFR 156.1230(b)(2) (see 84 FR 17454, 17568 (Apr. 25, 2019, effective June 24, 2019))). The Department cited Section 1321 of the ACA as its authority to promulgate the nondiscrimination provision. The authority section of the regulation also encompasses Section 1311 of the ACA, which prohibits QHPs from ''employ[ing] marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.'' [318]

(7) Summary of Regulatory Changes

The Department finalizes without change the proposed conforming amendments at 42 CFR 438.3(d), 438.206(c)(2), and 460.98(b)(3), and 45 CFR§ 147.104(e), 155.120(c)(ii), 155.220(j)(2)(i), and 156.200(e). It finalizes the proposed conforming amendment of the first sentence of § 440.262 without change, but retains the second sentence of that section without deleting it, and makes one grammatical correction to the second sentence. It finalizes the proposed conforming amendment of the first two sentences of § 460.112(a) without change, but retains the remainder of that subsection without deleting it.

With respect to 45 CFR 156.1230(b)(2), the proposed rule indicated it would amend § 156.1230(b)(3), but effective June 24, 2019, § 156.1230(b)(3) was redesignated as § 156.1230(b)(2). *See* 84 FR at 17568.

[315] *See* 81 FR 31376, 31428 (May 18, 2016) (''We noted that this section [92.207] is independent of, but complements, the nondiscrimination provisions that apply to . . . issuers of qualified health plans under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.'').

[316] 81 FR 12312 (''Issuers that receive Federal financial assistance, including in connection with offering a QHP on an Exchange, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act'').

[317] *Id.*

[318] 42 U.S.C. 18031.

Therefore, this rule finalizes the change at the redesignated location of the text at § 156.1230(b)(2).

IV. Regulatory Impact Analysis

The Department has examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 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, Public Law 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 Executive Order 12866 and reaffirms the principles, structures, and definitions governing regulatory review established there.

As discussed below, the Department has estimated that this final rule will have a beneficial effect on the economy greater than $100 million in at least one year. Thus, it has been concluded that this final rule is economically significant. It has, therefore, been determined that this final rule is a ''significant regulatory action'' under Executive Order 12866 and, accordingly, the Office of Management and Budget (OMB) has reviewed this final rule.

The executive summary at the beginning of this preamble contains a summary of this final rule in its summary of major provisions, and describes the reasons it is needed in describing the purpose of this final rule.

(1) 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 of appropriately reducing regulatory burden, in general, with respect to individuals, businesses and others, and from the ACA specifically.

Second, not pursuing any regulatory change would be inconsistent with various court rulings that have rejected or undermined the legal positions taken by the Department in the 2016 Rule. It would not, for example, ensure that the text of the Code of Federal Regulations accurately reflects the *vacatur* of the provisions including gender identity and termination of pregnancy as prohibited grounds of discrimination on the basis of sex. It also would not account for the decision of the Northern District of Illinois that the ''plain and unambiguous'' statutory text of Section 1557 indicated that a plaintiff could only use the enforcement mechanism of the underlying civil rights statute that corresponds to its claim. *Briscoe* v. *Health Care Serv. Corp.,* 281 F. Supp. 3d 725, 737–38 (N.D. Ill. 2017) (dismissing a Section 1557 claim for sex discrimination using a disparate impact standard, because plaintiffs cannot bring disparate impact claims under Title IX); *accord Galuten on Behalf of Estate of Galuten* v. *Williamson Med. Ctr.,* 2019 WL 1546940, at * (M.D. Tenn. Apr. 9, 2019); *E.S. by and through R.S.* v. *Regence BlueShield,* 2019 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *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 a motion to dismiss and rejecting the implication that 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, it would fail to account for the decisions of Federal courts in California, New York, and Iowa that 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). A court in Pennsylvania similarly 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 inconsistences between the Department's underlying regulations and the regulations and actions taken by other components of the Government. As applied to sex discrimination claims, the 2016 Rule set forth a definition of discrimination on the basis of sex under Section 1557 implementing Title IX that varied from the practice of other Departments. If the Department uses interpretations of Title IX that differ from other Departments and from the legal interpretation of the U.S. Government as set forth by the Department of Justice, it could lead to inconsistent outcomes across complainants and covered entities, with the problem 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 in light of the ordinary public meaning of discrimination on the basis of sex under Title IX. This final rule will also significantly restore the ability of States to establish policies in this area, based on their weighing of the competing interests at stake. As a policy matter, the Department believes State and local entities are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved. The Department's position will not bar covered entities from choosing to grant protections on the basis of sexual orientation and gender identity that do not conflict with any other Federal law. The Department has also determined that economic incentives, performance objectives, or

other related forms of regulation are neither appropriate nor feasible solutions to the problems to be solved.

The Department also considered simply repealing the 2016 Rule *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, as 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, and considers it worthwhile to set forth that commitment in a Section 1557 regulation which takes the position that the Department will use the enforcement mechanisms available under the statutes cited in Section 1557 and their underlying regulations. Additionally, the Department 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 also 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 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 OCR will enforce the ACA's nondiscrimination protections by replacing the 2016 Rule with regulatory provisions (1) applying the enforcement mechanisms provided under the civil rights statutes and related implementing regulations cited in Section 1557 to the 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 taglines mailing (materials, postage, and labor).[319] The Department adjusted the volume of mailings based on the average number of individuals served by each covered entity.[320] The 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 nondiscrimination notices would be largely duplicative of nondiscrimination notice requirements that already exist under Section 1557's underlying civil rights regulations.[321]

(2) Considerations for Cost-Effective Design

In this final rule, the Department replaces much of the 2016 Rule, to significantly reduce regulatory burdens and to return to the longstanding understanding of the underlying nondiscrimination obligations imposed by the civil rights laws referenced in Section 1557.

In the preamble to the 2016 Rule, the Department observed that 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 2016 Rule. 81 FR at 31446. Thus, in the 2016 Rule the Department concluded it did not expect covered entities to undertake additional costs with respect to that rule's prohibitions on discrimination on the basis of race, color, national origin, age, or disability, ''except with respect to the voluntary development of a language access plan.'' *Id.*

By finalizing this rule without the 2016 Rule's definition of sex discrimination and eliminating the requirements regarding notices, taglines, and visual standards in video remote interpreting services for LEP individuals, language access plans, and duplicative grievance procedures, the final rule also allows covered entities the freedom to order their operations more efficiently, more flexibly, and in a more cost-effective manner.

Accordingly, returning to the familiar longstanding requirements is a cost-effective way of (1) removing the unjustified burdens imposed by the 2016 Rule; (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.

(3) Methodology for Cost-Benefit Analysis

For purposes of this Regulatory Impact Analysis (RIA), the final rule adopts the list of covered entities and other cost assumptions identified in the 2016 Rule's RIA and that of the 2019 proposed rule. The use of assumptions from the 2016 Rule 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 Rule based several cost estimates on an expansive definition of Federal financial assistance, which significantly impacted the number of covered entities currently burdened by the 2016 Rule; thus, it is appropriate to use that definition for estimating cost relief. Such use, however, should not be interpreted as an endorsement or

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

[320] 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 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.

[321] *See* 45 CFR 80.6(d) (Title VI), 84.8 (Section 504), 86.9 (Title IX), 91.32 (Age Act).

acceptance of the definition for any other purpose.

The Department also does not ''carry over'' every assumption from the 2016 Rule for this final rule's RIA calculation. Most notably, the Department no longer considers its prior estimates of costs imposed due to the 2016 Rule's taglines requirement to be accurate or valid, and provides a more thorough and accurate estimate for purposes of this final rule.

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 and taglines. In addition, the Department quantitatively analyzes and monetizes the impact that this final 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 final 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 final rule.

The Department also considered the public comments submitted in response to the proposed rule. The Department appreciates the information and various perspectives provided in those comments, which are summarized below and for which responses are provided.[322]

(4) Cost-Benefit Analysis

a. Overview

In the 2016 Rule, the Department estimated $942 million [323] in costs (over five years) 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 31458–59 (at Table 5). As stated earlier, the Department estimated in the 2016 Rule that these costs would arise *primarily* from requirements imposed by the 2016 Rule with which covered entities were not already complying.[324] The Department specifically identified the 2016 Rule's interpretation of sex discrimination to cover gender identity and sex stereotyping,[325] and the 2016 Rule's consideration of language access plans for compliance purposes, as provisions triggering the imposition of new costs.[326] *See* 81 FR 31459—Table 5.

In 2016, the Department estimated that the 2016 Rule's nondiscrimination notice requirement would impose approximately $3.6 million in one-time additional costs on covered entities. 81 FR 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 31469. Thus, the total notice and taglines 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 underestimation, and thus this final rule's elimination of those requirements would generate a large economic benefit of approximately $2.9 billion over five years on the repeal of the notice and taglines provision.

Table 1 shows the expected cost savings from the repeal of the notice and taglines provision and the quantified costs to firms for training and revising procedures and policies.

TABLE 1—ACCOUNTING TABLE OF ECONOMIC BENEFITS AND COSTS OF ALL FINALIZED CHANGES

[In millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Savings:						
Total (undiscounted)	$643	$614	$585	$556	$528	$2,926
Total (3%)	624	579	536	494	455	2,688
Total (7%)	601	536	478	425	376	2,416
Costs—Quantified Costs:						
Total (undiscounted)	276	0	0	0	0	276
Total (3%)	269	0	0	0	0	269
Total (7%)	259	0	0	0	0	259
Net Total (undiscounted | 3% | 7%)						2,650 $2,319 (3%) $2,157 (7%)

Non-quantified benefits and costs are described below.

[322] The population, labor, and similar statistical data used in this RIA are also not changed from those used in the RIA in the proposed rule, because updating that data from the time of the proposed rule in June 2019 to the time of the publication of this final rule would not lead to substantive changes in the analysis.

[323] Throughout the regulatory impact analysis in the 2016 Rule, the 2016 estimates used 2014 dollars unless otherwise noted.

[324] 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'').

[325] 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.'').

[326] Although the 2016 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 2016 Rule. 81 FR 31454.

b. Generally Applicable Benefits and Burdens

i. Simplification and Flexibility

This final rule would result in other tangible benefits for covered entities. First, because this final rule is simpler and more easily administrable, it would be less likely that covered entities will 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, this final rule reduces 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 solicited comment regarding the nature and magnitude of such ongoing costs incurred by covered entities, and below the Department summarizes and responds to significant comments regarding the regulatory impact of changes to the notice and taglines requirements.

This final rule will also carry intangible benefits, including 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 will be free under the final 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.

ii. Policies and Procedures Concerning Gender Identity

In the proposed rule, the Department anticipated that the 2016 Rule likely induced many covered entities to conform their policies and operations to reflect gender identity as a protected category under Title IX. The Department requested and received public comments on the possible benefits and burdens related to changes in the proposed rule.

Comment: Many commenters contended that the proposed rule would lead covered entities to remove protections from transgender individuals in their policies and procedures. Commenters contended that these changes would lead to a wide range of burdensome results, including discrimination on the basis of gender identity and resulting negative health consequences, increased costs for treatment of such conditions, cost-shifting to transgender individuals, and increased burdens on the public health system due to the changes. Commenters also contended that similar results would occur from the Department's decision not to include sexual orientation nondiscrimination provisions in the proposed rule.

Response: The Department does not believe that this final rule will lead to significant burdens on entities due to changes to the gender identity language from the 2016 Rule, nor that the commenters have identified sufficient data to show that these negative consequences will occur or the extent to which they will occur. In December 2016, the *Franciscan Alliance* court preliminarily enjoined the gender identity provisions of the 2016 Rule on a nationwide basis, and more recently the court vacated those provisions. Consequently, this final rule's revisions to the provisions addressing gender identity do not change covered entities' obligations. Therefore, even though some entities may have changed their policies and procedures at the outset of the 2016 Rule, the Department concludes that because the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies and procedures concerning gender identity. In addition, as explained above, the 2016 Rule did not include language prohibiting discrimination on the basis of sexual orientation status standing alone as a form of sex discrimination. The Department therefore does not anticipate any material change to covered entities' policies concerning sexual orientation as a result of this final rule.

In addition, it is worth noting that many covered entities are located in jurisdictions that prohibit sexual orientation and gender identity discrimination under State or local laws. Therefore, such entities are unlikely to change their policies, training, or grievance procedures concerning gender identity as a result of this final rule. Moreover, nothing in this final rule, or in the court decisions, prohibits entities from maintaining gender identity nondiscrimination policies and procedures voluntarily, and the Department believes some covered entities will continue to do so.

If some entities change their policies and procedures based on this final rule, such a reversion may entail amending organizational nondiscrimination policies and training materials, and communicating those changes to employees. The process of voluntarily reverting to previous practices would likely result in net cost savings to covered entities. Otherwise these entities likely would not take such action. In addition, the Department believes that, if this final rule led to covered entities changing policies and procedures, some covered entities may no longer incur costs associated with processing grievances related to gender identity discrimination under Title IX, because such claims will not be cognizable under this final rule.

The Department, however, is uncertain as to the total number of covered entities that will change their policies and grievance processes to reflect the changes in this final rule. The reasons for this uncertainty include, as stated above, the fact that such changes would only be indirectly attributable to this rule, not caused by this rule, because previous court rulings have negated the gender identity provisions from the 2016 Rule for over three years, and this rule has no effect on State and local gender identity protections. The Department is not aware of data about how many entities might change their policies for these indirect reasons.

Similarly, 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 after publication of this rule—nor data to estimate how many of those individuals may experience the workplace and health-related negative consequences that many commenters contend will result from this final rule. The Department similarly lacks data to estimate what greater public health costs, cost-shifting, and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation of this rule. The Department reiterates that it believes these effects will be minimal, again due to the fact that gender identity provisions were vacated from the 2016 Rule by the *Franciscan Alliance* court before this rulemaking was finalized.

c. Baseline Assumptions

The following discussion identifies the economic baselines from which the Department measures the expected costs and benefits of this final rule. Its baselines includes the cost estimates in the 2016 Rule, in addition to data it has gathered since the 2016 Rule was implemented, as described in more detail below. The Department also considered public comments, and

responds to significant comments in this discussion.

Key assumptions track those set forth in the proposed rule and include the following: (1) The 2016 Rule triggered significant activity on the part of covered entities, generating both costs and benefits; (2) under the December 2016 nationwide preliminary injunction in *Franciscan Alliance,* and the October 2019 final judgment in that case, the gender identity and termination of pregnancy provisions of the 2016 Rule have been unenforceable and are now absent from the 2016 Rule, without regard to whether this rule is finalized; (3) covered entities were already generally complying with civil rights laws and related regulations that were in effect before the 2016 Rule, and so this final rule generally does not impose any new burden beyond those imposed prior to the issuance of the 2016 Rule; [327] (4) the projected costs from the 2016 Rule for years 1 and 2 have been incurred, and the projected costs from years 3, 4, and 5 have not been incurred; (5) repeal of the 2016 Rule's notice and taglines requirements does not affect notice or taglines requirements required by CMS guidance or regulations that do not reference, rely on, or depend upon the taglines requirements of the 2016 Rule; (6) 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 (7) covered employers are more likely to train employees who interact with the public than those who do not.

[327] OMB Circular A–4 discusses the practice whereby an RIA for a rule codifying a policy may include the impacts of that policy, even if the effects follow directly from an action by another branch of the federal government. The Circular notes that: ''In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.'' Although a baseline established prior to the *Franciscan Alliance* court's December 2016 and October 2019 orders would be considered analogous to the pre-statute baseline discussed in Circular A–4, given the existence of the RIA for the 2016 Rule, an assessment relative to a pre-*Franciscan Alliance* baseline would add little to the body of relevant analysis, and the longstanding duration of the court orders contributes to a lack of new data pertaining to certain alleged effects of language falling under those orders. For these reasons, the baseline established after December 2016, which isolates the effects most directly attributable to certain elements of this rule's finalization, is emphasized throughout the relevant parts of this RIA.

d. Covered Entities

i. Entities Covered by Section 1557

The 2016 Rule and this final rule 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 ACA, or any program or activity administered by an entity established under such Title. Covered entities under the 2016 Rule's definition [328] include the following:

(A) Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

The RIA for the 2016 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 2016 Rule, the covered entities consisted of the following:

(i) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).[329] Examples of these entities cited in the 2016 Rule's 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).

(iii) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).[330]

(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.[331]

(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) QHP 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

[328] As noted above, we use the list and number of covered entities and other figures from the 2016 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 2016 Rule's RIA for any other purpose related to this final rule.

[329] 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.*

[330] HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

[331] HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

through advance payments of premium tax credits and cost-sharing reductions, and at least 11 health insurance issuers operating in the State Exchanges).[332]

(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 Rule, the Department estimated that that rule likely covered 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, or 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 Rule's RIA estimate of the number of physicians receiving Federal financial assistance. As the 2016 Rule 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.[333] This figure represents about 69% of licensed physicians in the United States, based on the 890,000 licensed physicians reported in the Area Health Resource File.[334] 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.[335] Adding the approximately 614,000 physicians who receive Medicaid payments to the 296,500 physicians who receive meaningful use payments would yield 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,[336] the Department concluded in the 2016 Rule 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.

(B) Programs or Activities Administered by the Department Under Title I of the ACA

This final rule applies to programs or activities administered by the Department under Title I of the ACA. 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(*l*)), 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 ACA

This final rule applies to the health insurance exchanges established under Title I of the ACA. Such exchanges currently include the 12 State Exchanges (and D.C. Exchange), six State Exchanges on the Federal platform and 32 Federally-facilitated Exchanges.[337] Title I additionally establishes State advisory councils concerning community health insurance (section 1323) and certain reinsurance entities under the transitional reinsurance program (section 1341).

ii. Entities Covered by Title IX

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, App. 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 $585 million in additional average annual costs (over the next five years) that were not considered in the 2016 Rule. It is important to note that, while industry estimates prompted the Department to reassess the burdens imposed by the 2016 Rule, the Department conducted and relied upon its own cost analysis in developing the RIA for this final rule.

The 2016 Rule estimated $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 at 31453. As explained in detail below, the Department estimates the combined notice and taglines requirement has actually cost

[332] Qualified Health Plans Landscape Individual Market Medical (2015), *https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7*.

[333] 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.

[334] HRSA, Area Health Resource Files (2015), *http://ahrf.hrsa.gov*.

[335] 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*.

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

[337] CMS, State-Based Exchanges for Plan Year 2018 (Nov. 1, 2019), *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/state-marketplaces.html*.

covered entities hundreds of millions of dollars per year.

The 2016 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).[338] Thus, covered entities have 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.

This led to an extraordinary amount of mailed or electronically delivered communications by entities such as plan administrators and pharmacy benefit managers, including with every auto-ship refill reminder, formulary notice, and specialty benefit letter. Further, some other entities that operate in multiple States have interpreted the 2016 Rule as requiring them to include taglines for as many as 60 languages, or have included that many taglines in mailed or electronically-delivered 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.[339]

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,[340] 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 people [341] who share living arrangements.'' [342] By implication, 17.3 million individuals do not belong to a household,[343] and live in group quarters.[344] 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 communications from the health insurance Exchanges, the Department assumes the Exchanges send communications to the 11.8 million individuals enrolled in the individual market.[345] 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 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 million hospital admissions per year.[346] 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 taglines document, for a total of 105 million bills, assuming three bills per admission.[347] The Department assumes that 10% of the 105 million bills will have a notice and taglines document attached, for a total of 10.5 million notice and taglines 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 taglines documents. If more than three service providers bill a patient for a hospital visit, then the savings associated with this patient encounter will be greater than estimated due to the additional notice and taglines documents that the insurer would send with each additional explanation of benefits beyond the initial three assumed. If fewer than three service providers bill for a hospital visit, then the savings will be less due to the decreased volume of notice and taglines documents that the insurer would send because the insurer would send fewer than three explanation of benefits. Given that approximately 91% of the U.S. population is insured, the

[338] After publishing the 2016 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.*

[339] 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 with more than 15 languages, likely because of reasonable interpretations of the relevant provisions of the 2016 Rule, and the higher cost of attempting to tailor notices and taglines to individuals based on their specific State.

[340] 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 million as of March 14, 2018), *See https://www.census.gov/popclock.*

[341] 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.

[342] 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'').

[343] The Department subtracted 306 million individuals belonging to a household from the total U.S. population 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).

[344] 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.*

[345] *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.*

[346] CDC, Chartbook on Long-Term Trends in Health (2016), *http://www.cdc.gov/nchs/data/hus/hus16.pdf#317.*

[347] 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.

Department estimates that approximately 32 million of the 35 million hospital admissions are associated with insured patients (91% of 35 million hospital admissions).[348] This assumption does not account for variation in healthcare 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. Moreover, if the elderly, nearly all of whom are insured by Medicare, make up a disproportionate share of hospital admissions, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be higher.

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 taglines documents are attributable to the explanations of benefits sent by insurers (32 million admissions times three explanation of benefits). Using rounded values, approximately 107 million 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 physicians' offices approximately 990 million times each year.[349] Given that approximately 9% [350] 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) that 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.

Because experience and substantial feedback from healthcare insurers suggests a very high degree of compliance with the notice and taglines requirements when it comes to documents such as explanations of benefits, the Department presumes 100% compliance for purposes of this RIA. Anecdotal evidence, however, suggests that hospital and physician compliance with the notice and taglines 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. Although, according to the 2016 Rule's 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 2016 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 2016 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 at 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 on 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.[351]

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-sided [352] 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.

For postage, the Department estimates that the additional weight of the notice

[348] 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. http://news.gallup.com/poll/225383/uninsured-rate-steady-fourth-quarter-2017.aspx?g_source=Well-Being&g_medium=newsfeed&g_campaign=tiles.*

[349] 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 Rule.

[350] 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.*

[351] Source: Pharmaceutical Care Management Association (May 2, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006.*

[352] 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, the Department believes that a notice of that length is likely noncompliant with the 2016 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.*

and taglines 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).[353] 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 $0.20.[354]

For labor, the Department estimates the burden to download, print, and include these notices and taglines with all significant communications for an office clerk (Occupation Code No. 43–9061) with a mean hourly wage of $16.92/hour[355] plus an additional $16.92/hour in fringe benefits, or $33.84/hour for labor costs.[356] 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.[357] The Department uses the average of 2,880 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.

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) to $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 this final rule, due to transitions to electronic delivery for some communications affected by the 2016 Rule. The Department estimated, in the RIA for the Proposed Rule, that electronic delivery would reduce costs of affected communications by approximately 10–20% absent this final rule, shifting linearly from 10% in the first year to 20% in the fifth year following implementation (in other words, increasing by 2.5 percentage points each year). Survey results from Cognizant[358] indicate that 70 percent of respondents consider it important to be able to view medical care-related statements (*e.g.,* explanation of benefits documents) electronically, and that 42 percent are able to do so currently. But the same survey found that ''[a]doption rates are low for the digital services currently offered by health insurers, even for those that respondents rated as very important,'' with ''just about half of the members who were aware of'' a given digital service having actually ''used it.'' According to another survey by InstaMed,[359] 23% of providers offer some electronic billing, but even out of those providers who do, 58% still provide fewer than half of their bills electronically.[360] Moreover, it is likely that younger generations are the ones currently enrolling in e-statements; given that a disproportionate amount of health care services and products, especially pharmaceuticals, are consumed by the elderly, the communications containing the notices and taglines affected by this rule may be relatively unlikely to use e-statements. Therefore, as one end of a range of electronic delivery estimates, the Department maintains the earlier assumption of 10 percent in the first year, growing linearly to 20 percent in the fifth year after finalization, and departs from the preliminary RIA's assumption only in that the linear growth is extended past the fifth year. At the opposite end of the range of estimates, the electronic delivery rate is assumed to be 21 percent upfront (reflecting the higher of the two survey results cited above, with adjustment to account for the fact that in those surveys, 50% or less of patients offered electronic delivery have been accepting it) and 42 percent in Year 5 (reflecting the same survey, without such adjustment), with subsequent increases continuing at 5.25 percentage points per year.

In combining the two input ranges for Table 2 below—the cost per printed and mailed communication and the electronic delivery rates—the low ends are used together and the high ends are used together, to reflect that entities facing relatively high costs for printed communications would have greater incentive to shift to electronic delivery where feasible. The primary estimates relied on for Table 1, however, use simply the midpoint of each of the two input ranges.

Electronic delivery would eliminate postage costs, but may to a certain extent 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.

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 $0.58 billion per year, over the first five years, after adjusting for electronic delivery.

As discussed above, the proposed rule noted that, with repeal of the 2016 Rule requirements, the Department assumed that two other regulatory requirements for taglines would also be fully repealed because they depend on, or refer to, the 2016 Rule for authority for the taglines 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 QHP issuers (*see* HHS Notice of Benefit and Payment Parameters for 2016; 2016 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. Those

[353] *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.*

[354] *See* U.S. Postal Service Postage Rates, *https://www.stamps.com/usps/current-postage-rates/.*

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

[356] 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.

[357] *See, e.g.,* Pitney Bowes, ''Folders and Inserters,'' *https://www.pitneybowes.com/nz/folders-inserters.html.*

[358] *See https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf.*

[359] *See https://www.instamed.com/white-papers/trends-in-healthcare-payments-annual-report/.*

[360] *See https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf* and *https://www.instamed.com/white-papers/trends-healthcare-payments-report-2018/.*

two other regulations have not yet been amended in this respect, but the Department clarified above that because those requirements inform entities they will be deemed in compliance if they are in compliance with the Section 1557 rule's notice and taglines requirement, and because the latter has now been repealed by this final rule, covered entities do not need to independently comply with those two other regulatory requirements cross referencing the Section 1557 rule. As a result, these estimates continue to assume this final rule will result in cost savings with respect to those requirements.

The Department also assumes that health insurance entities would not voluntarily append notices and taglines to routine monthly premium statements absent the 2016 Rule, but are doing so because of it (or because of a requirement in another regulation that bases its requirement on the 2016 Rule's requirement).

TABLE 2—ANNUAL SAVINGS FROM REPEAL OF REQUIREMENT TO PUBLISH AND MAIL NOTICES AND TAGLINES, BY VOLUME OF TRANSACTIONS PER TYPE PER YEAR AFTER ACCOUNTING FOR ELECTRONIC DELIVERY

[in millions]

	Count	Estimated low Savings ($0.035/unit)	Estimated high savings ($0.32/unit)
Exchange eligibility and enrollment communications	17.7	Year 1: $1 Year 5: $0	Year 1: $4. Year 5: $3.
Annual notice of benefits	123	Year 1: $4 Year 5: $3	Year 1: $31. Year 5: $23.
Explanations of Benefits—hospital admissions	96	Year 1: $3 Year 5: $3	Year 1: $24. Year 5: $18.
Explanations of Benefits—physician's visits	941	Year 1: $30 Year 5: $26	Year 1: $238. Year 5: $175.
Medical bills—hospital admissions	11	Year 1: $0 Year 5: $0	Year 1: $3. Year 5: $2.
Medical bills—physician visits	99	Year 1: $3 Year 5: $3	Year 1: $25. Year 5: $18.
Pharmacy-related notices	2,900	Year 1: $91 Year 5: $81	Year 1: $733. Year 5: $538.
Total, accounting for electronic communications	4,188	Year 1: $132 Year 5: $117	Year 1: $1,059. Year 5: $777.

The primary estimate of annual savings is approximately $0.63 billion in Year 1 and $0.51 billion in Year 5 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 2016 Rule's rescission generates for the healthcare sector as set forth in Table 2. These requirements include (1) Group Health Plans and Health Insurance Issuers requirements; [361] (2) Navigator requirements; [362] (3) Non-Navigator Assistance Personnel requirements; [363] Medicaid requirements; [364] Medicaid Managed Care requirements; [365] CHIP requirements; [366] CHIP Managed Care requirements; [367] Hospitals Qualifying for Tax-Exempt Status requirements; [368] and Medicare Advantage (Part C) and Prescription Drug Plans (Part D) requirements.[369]

Comment: Some commenters indicated that the notice and taglines requirements that the Department proposed for removal led to substantial costs that the Department understated. For example, they contended costs may be higher than the Department estimated in the proposed rule because plans had to revise internal documents, incur significant IT costs, and work with outside vendors to implement the 2016 Rule. Commenters also contended the 2016 Rule resulted in significant annual printing costs.

One commenter calculated that the costs of the mailings related to pharmacy services yielded additional costs of $1 billion a year. The commenter supported the Proposed Rule's RIA aggregate estimate that the requirement would save plans $101 to $928 million a year and provided a specific example in which an affected entity reported incurring $3.9 million in printing costs and $4 million in operations costs to send 55.5 million communications.

Another company reported almost $1 million in annual increased expenses on toner, developer, paper, and postage related to notice and taglines requirements. Another commenter stated the costs associated with complying with the 2016 Rule's requirement accounts for 4.5% of one company's budgeted operating income. Some commenters also stated the proposed rule would significantly reduce the administrative burden placed on providers, saying that what constitutes a ''significant'' communication has been insufficiently clear and has resulted in broad interpretations and providers using the taglines in almost every document.

Some commenters estimated that the dental profession has spent over $240 million to date on compliance with the 2016 Rule. The commenter noted that the time and cost for dental offices to interpret the regulations, print documents, alter existing publications, and modify websites has been significant. Several dental offices believe repealing the notice and taglines requirements will lead to cost savings and will allow staff to spend time on appropriate patient care and communication instead.

One commenter explained that in its Pennsylvania line of business, it serves

[361] 45 CFR 147.136(e)(2)(iii) and (e)(3), and § 147.200(a)(5).

[362] 45 CFR 155.215(c)(4).

[363] 45 CFR 155.215(c)(4).

[364] 42 CFR 435.905(b)(3).

[365] 42 CFR 438.10(d)(2) through (3), (d)(5)(i) and (iii), and (j).

[366] 42 CFR 457.340(a).

[367] 42 CFR 457.1207.

[368] 26 CFR 1.501(r) through 1(b)(24)(vi).

[369] Medicare Marketing Guidelines § 30.5.1, *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html.*

800,000 persons and sends them 2-page double-sided notices and taglines 6,205,000 times a year under the 2016 Rule, resulting in $245,175 in annual mailing costs. The commenter noted it has similar experiences in all of its Medicaid lines of business.

Other commenters suggested the Department overestimated the costs of the 2016 Rule's notice and taglines requirements. One association stated that the Department's estimate in the proposed rule overestimated by failing to account for notices generated by a machine, included in bulk mailings, or facilitated through the use of computers. The commenter also believed that, while electronic delivery would eliminate postage costs, it would not shift the cost of paper and printing to the consumer/beneficiary/patient, stating it is unlikely that a significant percentage of individuals would download and print documents sent to them electronically. Similarly, the commenter contended the Department failed to account for the significant degree to which communications can be provided electronically and the degree to which some entities, such as insurance plans, have already been doing so for years.

Another commenter, however, agreed with OCR's calculation that the notice and taglines requirement has resulted in the inclusion of one to two sheets of paper. Similarly, one commenter stated it implemented multiple versions of the two-page notice and taglines on thousands of documents in its businesses, which consumed significant resources. The commenter noted that the requirements also impacted covered entity partners as well, particularly print vendors.

Some commenters asked the Department to separate out costs for providing notices as distinct from providing taglines, and for posting notices as distinct from mailing them.

Response: The Department appreciates the comments regarding the costs of the 2016 Rule's notice and taglines requirements. The Department agrees with commenters who contend that the requirements imposed significant and costly burdens far beyond the estimates set forth in the 2016 Rule. The Department finalizes this rule in significant part to relieve those burdens.

Some commenters contended the Department's estimates in the proposed rule were understated, and others contended the Department's estimates were overstated. The comments generally provided data from specific entities or circumstances.

The Department's estimate of the average cost of mailings is based on data received from covered entities across the affected industry, and generally takes into account processes and methods used in mailings such as machines, computers, and bulk handling. Although the Department suggested that some patients and beneficiaries might print notices electronically mailed to them, the Department did not factor those potential costs in its estimate. To the extent that commenters contended the Department failed to consider the extent to which notices and taglines are delivered electronically, this is incorrect, as the Department's preliminary estimates included downward adjustments to its estimates based on electronic delivery, and its revised estimates reflect a broader range of potential electronic delivery rates. Moreover, other commenters contend that they continue to experience significant costs based on non-electronic delivery—contending in some cases that the Department's estimates of those costs were understated.

Commenters were correct to identify that some costs, such as revising internal documents, IT costs, and setting up relationships with outside vendors, resulted from the 2016 Rule. The Department does not estimate that this final rule will lead to cost savings with regard to those types of expenses, however, because they are generally sunk costs that covered entities incurred at the time of the 2016 Rule and will not be able to recover as a result of this final rule. This final rule does not prohibit entities from continuing to provide the type and number of notices and taglines required by the 2016 Rule, but gives covered entities the flexibility to not provide them.

The Department declines to accept the suggestion of some commenters that the Department separate out the costs of notices from the costs of taglines. Information from covered entities indicates that notices and taglines are usually provided together, often on overlapping pages. Because this final rule removes both requirements, the Department's estimates are intended to cover the costs of both notices and taglines.

Comment: One commenter stated that the Department improperly relied on healthcare corporations for its fact-finding and analysis in the proposed rule. In particular, conclusions that the repetitive nature of notices and taglines dilute messages, that beneficiaries do not want to receive them, and that there is no evidence that more beneficiaries have sought language assistance because of the notices, were largely gathered from the covered entities themselves.

Response: The Department relies on its own data, publicly available data, and data submitted by members of the public—including covered entities—to attempt to estimate the impact of its regulations. The Department takes into consideration the sources of the data it considers, and attempts to weigh all such data appropriately based on the information the Department has available to it.

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, healthcare for non-English speakers by reducing their awareness of available translation services.

Comment: Some commenters generally supported the Department's assessment that the benefits from the notice and taglines requirements were hard to quantify and likely not significant. A health insurance plan commenter stated that since the implementation of the 2016 Rule, it has not experienced significant changes in its member demographics or languages spoken, and has not seen any notable increases in requests for translation services. One commenter also stated that its pharmacy benefit manager found that since 2017, the volume of valid complaints about discrimination are less than 1% overall and could be better handled by personnel already in place. The commenter stated further that since 2017, it has filled approximately 3.5 billion prescriptions and mailed nearly half a billion beneficiary communications. In this time period, approximately 0.002% (26 of 14,000) of calls made to the discrimination hotline were closely related to a complaint. Several commenters stated they did not see a significant increase in requests after the 2016 Rule required notices and taglines, but instead experienced relatively flat demand.

Some commenters also expressed concerns regarding wastefulness of the notice and taglines. A commenter calculated that it has spent nearly $16 million since 2017 to accommodate the current requirements and will save at least $3.5 million annually under the proposed rule. One commenter suggested that an analysis of the impact of the notice and taglines should take into account the content and frequency of the notices, overall consumer health literacy, costs and administrative burdens, and whether notices are truly meaningful to consumers.

Other commenters suggested that the 2016 Rule's notice and taglines requirements likely yielded benefits to intended individuals. A hospital commented that it observed a 10% increase in the volume of interpreter service encounters each year over the last three years. Another commenter stated that it saw a 28% reduction on its per-member per-month claims cost with its Spanish-speaking population. Several commenters from a variety of organizations request an analysis of the impact on those who most use the services affected by the proposed provision (LEP individuals) and on those who provide services to the impacted population. Several organizations, including a State government, also contended that LEP individuals are a significant portion of the population and tend towards poorer health outcomes. They also suggested that removing the notice and taglines requirements may cause such individuals to delay care or not receive care until their medical issues are more severe and costlier to treat, and they urged the Department to estimate such costs.

Another commenter stated that even though HHS justified the proposed rule in part by citing data that over three-quarters of the U.S population over the age of 18 speak only English at home and are not well served by taglines or notices, the commenter believes that if a quarter of the population does not speak English at home that is an argument against repealing the notice and taglines.

Several commenters suggested repeal of the taglines provisions may negatively impact LEP individuals. One commenter cited a study claiming that health inequities cost the U.S. economy $309.3 billion a year.

Response: The Department appreciates the comments concerning the effectiveness and benefits of the notice and taglines requirements from the 2016 Rule. As noted in the proposed rule, previously received reports from covered entities are consistent with some public comments suggesting that the 2016 Rule's requirements did not appreciably increase the use of translation services. One such report indicated that utilization of translation services did not appreciably rise after the 2016 Rule's imposition of notice and taglines requirements.[370] Although some commenters contended that they experienced an increase in translation services after the 2016 Rule, others reported a different experience. The Department generally agrees with the latter, and the difference in reports from different commenters and other sources reinforces the Department's view of the difficulty of attempting to calculate the 2016 Rule's benefits to individuals needing translation services. The Department does not believe it has data enabling it to fulfill the request of commenters who urged the Department to calculate the value of such benefits lost as the result of this final rule, as distinct from data that more generally estimate costs resulting from inequality or delay in care.

As noted in the proposed rule, there are other reasons to believe the 2016 Rule's notice and taglines requirements imposed burdens disproportionate to potential benefits for intended beneficiaries. 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 five speak only English at home, followed by Spanish (13%).[371] Although a commenter contends this statistic provides an argument in favor of maintaining multi-language taglines, the Department disagrees regarding a requirement to send such taglines where almost 80% of the recipients likely speak only English at home, and a majority of the remainder spoke English ''very well.'' [372] Additionally, of persons selecting a written language preference when registering for coverage on the HealthCare.gov platform for 2017, 90.29% selected English, followed by 8.23% who selected Spanish.[373] These data indicate that, for the large majority of people who receive them, the required language taglines mailings provide little to no benefit because they are already proficient English speakers with little need for translation services.

Furthermore, the 2016 Rule's requirements added 47 languages to existing language access requirements, but that only increased access to 0.4% of the entire U.S. population. This was after broadly defining ''limited English proficiency'' to include those who speak English ''well'' but not ''very well.'' [374] The Department's Office for Civil Rights also produced a list of the top 15 languages in each State; however, 26 of the languages on OCR's list are spoken by less than 0.004 percent of the population. As a result, in some States, especially those with sparser populations, the 2016 Rule required health insurance issuers to provide taglines services in languages spoken by very few people in the State. For instance, in Wyoming, issuers needed to 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 were required to provide notices to account for approximately 80 speakers of Pennsylvania Dutch; and in Puerto Rico, issuers had to provide taglines notices to account for approximately 22 Korean speakers and 22 French Creole speakers.[375]

The Department also continues to believe that the notice and taglines required by the 2016 Rule imposed burdens on many recipients and may interfere in their receipt and understanding of important healthcare information. Prior to the proposed rule, the Department received many communications from beneficiaries and advocacy groups complaining about the excessive amount of paperwork they receive. These individuals and groups

[370] *See* Aetna (May 1, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005.*

[371] 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), *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).

[372] 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), *https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US.*

[373] 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.

[374] *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-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/tableservices/jsf/pages/productview.xhtml?pid=ACS_14_5YR_B16001&prodType=table* (2016 year estimates).

[375] 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.*

explained that few people read the notice and taglines and most ignore the last pages of lengthy health documents. Additionally, documents that contain a significant number of pages that recipients do not value can often 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 communications coincide with the views of some commenters and generally support the Department's conclusion that the 2016 Rule has resulted in ''cognitive overload,'' where individuals experience a diminished ability to process information when inundated with duplicative information and paperwork. These frustrations, though difficult to quantify, are reasonable to expect given the large volume of healthcare 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.

It is also noteworthy that other rules exist to benefit the persons whom the 2016 Rule's notice and taglines requirements intended to assist. Regulations under Section 504 of the Rehabilitation Act generally 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 2016 Rule required frequent mailed notification of the availability of auxiliary aids and services, the Department suggested in the proposed rule that repealing the notice of nondiscrimination requirement may result in additional societal costs, such as decreased utilization of auxiliary aids and services by individuals with disabilities due to their reduced awareness of such services. Some commenters agreed, but they did not suggest any way to reliably calculate such effects, and the Department is not aware of any. This impact may also be limited because the Section 504 regulations already require recipients of Federal financial assistance employing fifteen or more persons to provide notice to participants, beneficiaries, applicants, employees, and other interested persons of the availability of such aids and services. 45 CFR 85.12 and § 84.22(f).

Additionally, some commenters contended that repealing the notices and taglines may lead to persons not being made aware of their right to file complaints with OCR, and that some of those persons may suffer remediable grievances but will not complain to OCR absent notices informing them of the process. The Department continues, however, to not be aware of a way to quantify those potential effects. In addition, as noted above, the regulations implementing Section 1557's four underlying statutes already contain notice provisions, *see* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act), and therefore this potential cost may be minimal.

g. Cost Savings From Changes to Language Access Plan Provisions

Although the 2016 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 2016 Rule. 81 FR at 31454.

Comment: One commenter noted that physician group practices report financial losses and significant costs when treating patients that require interpretation or translation services. The commenter stated that providing reimbursement at the Federal level would help offset extra costs incurred to provide these services free of charge and reimburse group practices for increased upfront costs and time required to care for LEP individuals. The commenter contended that face-to-face interpretation services cost between $50 and $150 per hour and may include a minimum hour requirement and transportation fee. The commenter points to one practice that reported being billed nearly $300 for a single in-person interpreter service this year due to a minimum rate and transportation fee. The practice reported paying $1,200 in interpretation fees for one month for nine individuals.

Response: The Department appreciates these comments. With respect to serving LEP patients, this final rule gives more flexibility to covered entities, while specific obligations to patients will be governed by criteria that has been set forth in longstanding guidelines. It is not within the scope of this rule to provide for Federal reimbursements.

Comment: Several commenters claim the proposed rule failed to consider the benefits to LEP individuals that will be lost by repealing certain provisions. Such commenters state there are tens of millions of LEP people who rely on protections from Section 1557. Another commenter notes that four million Medicare beneficiaries are LEP. A commenter notes that only 15 States use the Medicaid option to reimburse for interpretation. Commenters state that the language access protections in the 2016 Rule benefit Latino/a patients, Asian American and AAPI patients, LEP gender-based violence victims, low-income LEP patients, older adults, people with disabilities, and lower-income older adults.

Some commenters contend that the rule will lead to reduced awareness of language services by LEP persons and by the general public about their rights and protections. One commenter stated that if the rule is finalized, organizations like community health centers that are not funded or do not receive reimbursement for language services will face increased burdens when fewer clients will be aware of their language access rights and likely turn to them instead of to covered entities.

Commenters opposing the proposed rule claimed it would lead to inequality and a reduction in the quality of language access available; the avoidance of care, leading to worsened conditions and avoidable higher-cost hospital services; increased costs due to missed appointments, delayed care, and ''non-compliant'' self-care; increased Emergency Room use; lower preventive care access and use; malpractice costs; avoidable hospital readmissions; higher rates of uninsurance; unnecessary tests and procedures; higher rates of mortality; misunderstood diagnoses and prognoses leading to poor quality of care; and costs due to lower rates of outpatient follow-up, poor medication adherence, and lack of understanding of discharge diagnosis and instructions.

One commenter claimed that HHS's estimate that covered entities would save around $17.7 million per year by eliminating references to language access plans overlooks larger healthcare savings generated by access to interpretation services. Two commenters point to a 2017 study finding that easily accessible language interpretation services avoided an estimated 119 readmissions that were associated with savings of $161,404 per month in an academic hospital. Two commenters pointed to a 2010 report finding that at least 35 of 1,373 malpractice claims were linked to inadequate language access.

Another commenter cited a report that found that 2.5% of one malpractice carrier's closed claims involved language issues that cost the carrier over $5 million in damages, settlements, and legal fees. Costs included damages paid to patients, legal fees, time lost when defending the lawsuit, loss of reputation and patients, fear of possible monetary loss, and stress.

Response: The Department acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness. As noted above, however, this final rule continues to provide protections for LEP individuals and commits the Department to enforcement of Section 1557. The Department believes, therefore, that the negative effects predicted by some commenters may be mitigated by the continued commitment to enforcement of Section 1557. The data cited by commenters either do not assess the overall impact of the 2016 Rule as compared to a regime with continued enforcement of Section 1557, or address information about broader matters without providing a method for the Department to specifically analyze how this final rule will cause the effects commenters fear may occur. In this respect, the Department believes that malpractice carriers themselves, not Federal civil rights regulators, are best equipped to determine what practices malpractice carriers should require for the sake of reducing their own financial risk.

Therefore, in consideration of the public comments and the Department's analyses, the Department adopts the estimates from the proposed rule concerning changes to language access plan provisions.

In the proposed rule, 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. Throughout, we assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is therefore estimated to be $109.36 based on Bureau of Labor Statistics (BLS) data for 2018.[376] These are within the general range provided by some commenters' description of costs they have experienced.

The Department estimated that approximately 269,141 entities could potentially make changes and develop language access plans in response to the 2016 Rule, as part of the requirement to take reasonable steps to provide meaningful communication with LEP individuals (calculated by reducing the 275,002 affected entities by the 5,861 hospitals and nursing care facilities that were already subject to language access plan requirements under Medicare Part A). The Department further assumed that only 50% of the identified entities would actually make changes to implement a language access plan. If the actual compliance rate were higher, the costs would be higher. These assumptions imply that the total cost of developing language access plans will be approximately $44.1 million (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. The Department assumes sunk costs cannot be recovered by this rule, and therefore that initial language access plan development costs attributable to the 2016 Rule cannot be recovered.

By repealing the provision of the 2016 Rule regarding the Language Access Plans, the Department estimates annual savings are $14.7 million.

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

This final rule repeals 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 final rule, covered entities no longer have to incur certain labor costs associated with processing grievances related to sex discrimination complaints as they relate to gender identity as defined under the 2016 Rule because such definitions would be repealed and no longer binding. This repeal would not, however, affect the independent obligations that entities covered by Section 1557 have 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.[377]

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

The 2016 Rule estimated that, in years three through five of the 2016 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 at 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%. *Id.* The 2016 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). *Id.* The Department continues to assume that OCR's increase in caseload attributed to the 2016 Rule reasonably informs the increase in grievance processing that covered entities will experience.

Based on OCR's tracking of Section 1557 complaints received from promulgation of the 2016 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 2016 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 preliminarily enjoined on a nationwide basis by a Federal court from enforcing claims based on the 2016 Rule's definition of sex discrimination, and those provisions have now been vacated by the same court.

The 2016 Rule asserted that private parties have the right to challenge a violation of Section 1557 or the 2016 Rule in Federal court, independent of OCR enforcement or involvement. 45 CFR 92.302(d). In the preamble to the 2016 Rule, the Department suggested that the ability for private parties to sue

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

[377] *See, e.g.,* 45 CFR 84.7(a) (HHS regulations implementing Section 504) (requiring a written process to be in place for handling grievances alleging disability discrimination), § 86.8(a) (HHS regulations implementing Title IX) (requiring a written process to be in place for handling grievances alleging sex discrimination).

under the 2016 Rule would result in covered entities bearing increased compliance costs. 81 FR at 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 preliminary injunction did 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, under this final rule the Department would no longer assert in the regulatory text or the preamble to the rule that a private right of action exists for parties to sue covered entities for any and all alleged violations. Because the issue of whether a person has a right to sue in Federal court under Section 1557 is one determined by the courts themselves and not by the Department's regulations, the Department does not estimate that this change will lead to any economic impact.

Although this final rule removes from the 2016 Rule the expansive inclusion of gender identity and sex stereotyping in the definition of sex discrimination, a court has recently vacated the gender identity provisions of the 2016 Rule. Regarding sex stereotyping, to the extent the 2016 Rule used that term to encompass gender identity, the sex stereotyping provision had no real-world effect after the court decision. To the extent sex stereotyping in the 2016 Rule did not encompass gender identity, the Supreme Court already recognized a degree of relevance of sex stereotyping in sex discrimination claims. This is discussed in more detail in the section above on sex-based discrimination. Therefore, the Department does not believe there would be a direct material economic impact regarding grievance procedures from this final rule's change in the definitions concerning sex stereotyping.

In addition, 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 2016 Rule.

In the proposed rule, the Department estimated that covered entities would have experienced a 3% increase in gender identity and sex stereotyping grievance claims over the long term due to the 2016 Rule, and half of that caseload (1.5%) could have been due to the 2016 Rule's language encompassing gender identity and sex stereotyping claims in States where covered entities are not otherwise required to handle those claims. The proposed rule estimated an annual savings in labor attributed to a 1.5% decrease in grievance caseload as $123.4 million, representing 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.

Nevertheless, in this final rule the Department does not estimate a cost savings concerning grievance procedures. This is because, as stated repeatedly elsewhere, the court order vacating the gender identity provisions of the 2016 Rule means that this final rule's changes concerning gender identity will have no direct material economic impact. The *Franciscan Alliance* court order forms the new legal baseline in this respect, and therefore the primarily-emphasized economic baseline, for the purposes of this estimate. To the extent sex-stereotyping claims remain viable, they were already authorized by the Supreme Court's longstanding interpretation of sex stereotyping.

i. Additional Costs for Training and Familiarization

To comply with the final rule, the Department anticipates that some covered entities may incur costs to re-train employees in order to realize potential longer-term costs savings from the deregulatory aspects of this final rule's changes. 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.

i. Number of Covered Entities That May Train Workers

The 2016 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. The Department assumes, for purposes of this analysis, that the 2016 Rule's estimate was an accurate and reasonable basis for calculating costs arising from the need to provide training regarding the 2016 Rule.

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE

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 healthcare services	21,668
6219	All other ambulatory healthcare 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

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE—Continued

NAIC	Entity type	Number of firms
	Navigator grantees	100
Total Entities		275,002

ii. Number of Individuals Who Will Receive Training

The first category of healthcare 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 healthcare 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 healthcare: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of healthcare 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. Healthcare 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 healthcare staff that the Department assumes will receive training is healthcare 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 healthcare 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.

iii. Total Costs of Training

The 2016 Rule estimated that covered entities would incur $420.8 million in undiscounted costs to train employees on the requirements of the Rule, distributed roughly evenly over the first two years after the 2016 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 2016 Rule's new sex discrimination requirements would induce covered entities to engage in additional ''comprehensive training.'' 81 FR at 31447.

For the purposes of this regulatory impact analysis, the Department assumes covered entities would face similar costs to retrain the workforce on this final rule's requirements.[378] However, because some covered entities will avoid incurring training expenses when they are not required to (as they will not be subject to the final rule), and because several States with large populations already prohibit gender identity discrimination in healthcare, the Department further assumes that only 50% of covered entities would modify their policies and procedures to reflect the changes in the final rule. Moreover, to the extent entities were motivated to provide training specifically due to the sex discrimination components of the 2016 Rule, a court has already vacated the gender identity and termination of pregnancy provisions of the 2016 Rule, and this final rule simply amends the Code of Federal Regulations to conform to the *vacatur* in that regard. The Department further assumes that 50% of covered entities, or 137,501, would train their employees to reflect the changes in this final rule. As in the 2016 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 2016 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 this final rule. Therefore, the Department 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 effect on projected costs.

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 final rule's clarification of the application of Section 1557, 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 this final rule. The Department selects four hours, the midpoint of this range, for the analysis. The Department further assumes that an average of three of these hours would be spent by a mid-level manager equivalent to a first-line

[378] Training costs in the 2016 Rule relied upon 2014 wages. *See, e.g.,* 81 FR at 31451 (estimating the median hourly wage for occupation code 29–1000 at $36.26, unloaded, at *https://www.bls.gov/oes/special.requests/oesm14nat.zip* .

supervisor (Occupation code 43–1011), at a cost of $57.06 per hour [379] after adjusting for overhead and benefits, while 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 hour [380] after adjusting for overhead and benefits. The total cost for the estimated 137,501 covered entities to make their policies and procedures consistent with the final rule's changes is estimated to be approximately $39.9 million following implementation of this rule.

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 precisely.

k. Other Benefits or Costs

The 2016 Rule's regulatory impact analysis did not include an economic cost-benefit analysis of the regulation's impact on health insurance benefit design. The Department lacks sufficient data on how much burden the 2016 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 Department received several comments concerning the impact of the proposed rule on issues concerning discrimination on the basis of LGBTQ status, sex stereotyping, termination of pregnancy, and other provisions.

Comment: Many commenters objected that the Department did not estimate the potential for increases in the denial, delay, or substandard delivery of healthcare services from the rule's changes concerning gender identity.

One commenter suggested exploring quantitative analysis based on a survey by Harvard University and National Public Radio (NPR) in which 18% of LGBTQ people polled in 2017 reported foregoing care that they need, including preventive care, due to fears of or experiences of discrimination (including 22% of transgender people).[381] The comment estimated that this regulation will cost $1.4 billion in excess costs over the next ten years simply to treat cases of four particular cancers that would have been detected and prevented by screening, and that there will be an 18% increase in preventable mortality from these four cancers among LGBT people. The comment cited the 2016 value of a statistical life (VSL) used by the U.S. Department of Transportation to estimate these preventable deaths as being worth $39 billion to the U.S. economy over the next ten years.

Another commenter provided a list of potential sources of economic costs the proposed rule could produce concerning transgender patients, including out-of-pocket costs shifted because of transgender exclusions; increased costs from healthcare issues exacerbated by discriminatory delay or denial of care; increased costs related to sex coding; or increased costs due to substandard delivery of care. Other commenters similarly contended that literature on increased costs due to discrimination could be used to estimate economic costs. But such commenters did not provide quantitative values of such costs, or of ways to attribute the costs or portions thereof to this rulemaking.

One healthcare provider stated that they have not incurred any unreasonable costs in delivering care to its LGBTQ patients from complying with nondiscrimination protections based on sexual orientation and gender identity. The commenter added that adopting transgender-inclusive healthcare practices can reduce the costs associated with complications that arise when care is delayed or denied transgender patients due to discrimination.

One commenter stated that patients without primary care would experience an increase in emergency room visits, which would result in increased costs for the healthcare system—including from hospitals' and the government's absorbing and subsidizing the costs of uninsured patients.

Commenters raised similar comments concerning sexual orientation as did the commenters discussing gender identity or LGBTQ issues more broadly, contending the proposed rule should estimate the impact of not including protections against sexual orientation discrimination.

Response: The Department appreciates the comments concerning the regulatory impact of this final rule's changes concerning gender identity.

This rule commits the Department to vigorous enforcement of the nondiscrimination provisions of Section 1557 and Title IX as incorporated therein, according to the plain meaning of the protections set forth in those statutes. In addition, the gender identity provisions of the 2016 Rule were preliminarily enjoined on a nationwide basis by a court from December 2016 until October 2019, when they were vacated entirely. As a result, this final rule maintains the status quo with respect to gender identity under the enforcement of the Section 1557 rule.

Based on the Department's review of the public comments, the commenters did not provide, and the Department is not otherwise aware of, reliable data or methods to calculate the economic impacts concerning gender identity that they allege would be attributable to this final rule. Commenters cited various sources of data, but many were either too narrow in not providing a basis to estimate the impacts of this rule nationwide, or were too broad in discussing aspects of the healthcare system but not impacts of this specific rule. For example, citations to data about the percent of transgender persons who forgo care due to fears or experiences of discrimination, and a calculation of the costs to the healthcare system resulting from such occurrences, are not sufficient to estimate the effects of this final rule itself, due to court orders preliminarily enjoining and then vacating provisions in the 2016 Rule, State and local laws that already provide gender identity protections, and other factors that prevent the Department from showing that this final rule is causing those effects. For example, one poll cited by commenters was conducted in 2017, when the 2016 Rule was already in place, but when its gender identity provisions were preliminarily enjoined. So it is not clear from that poll that the 2016 Rule yielded the benefits the commenters say it did, and it is even less clear how this final rule will remove those benefits. Generally, the Department's review of comments is that concerns about increased costs to LGBT persons from this final rule do not offer sufficient quantitative evidence for the Department to provide an estimate along these dimensions.

Finally, as discussed above, because the 2016 Rule contained no prohibition on sexual orientation discrimination in the 2016 Rule, the Department does not deem there to be an economic impact resulting from this final rule with respect to sexual orientation discrimination.

[379] BLS, Occupational Employment and Wages, May 2018, *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[380] *Id.*

[381] NPR, ''Discrimination in America: Experiences and Views of LGBTQ Americans'' (Nov. 2017), available at *https://www.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf.*

Consequently, commenters' warnings of effects of this rule's changes on these issues do not give rise to impacts that are properly attributable to this rule and that the Department believes can be estimated for the purposes of this analysis.

Comment: One commenter contended that the Department should include analysis of the consequences of removing sex stereotyping language from the rule. The commenter suggested that costs of this rescission could include increased confusion for patients and covered entities, increased discrimination based on sex stereotyping with attendant economic and non-economic costs to patients and the public health system, increased need for legal advice, and increased litigation.

Response: To the extent that sex stereotyping language from the 2016 Rule was interpreted to encompass gender identity, court orders have preliminarily enjoined and now vacated those provisions. Therefore, this final rule does not directly induce changes in this regard. To the extent that sex stereotyping is a recognized category of sex discrimination under longstanding Supreme Court precedent, this final rule commits the Department to continuing to vigorously enforce Title IX through Section 1557, and therefore the Department estimates that this final rule will not have any material effect on the scope of sex stereotyping claims as authorized by Title IX and Section 1557.

Comment: A commenter objected that the proposed rule did not estimate the economic impact of withdrawal of Federal guidance and technical support concerning the 2016 Rule.

Response: All guidance and technical support concerning the 2016 Rule was withdrawn by operation of the preamble to the proposed rule, which itself is a guidance document—not directly by this final rule. The outdated guidance documents are in the process of being removed from the Department's websites. The Department is not aware of any data that would allow it to estimate the effects of changes to its sub-regulatory guidance. To the extent that certain guidance and technical support concerned provisions of the 2016 Rule that were enjoined and vacated, this final rule is not the direct cause of the Department's non-enforcement of those provisions.

Comment: Some commenters contended that the proposed rule would lead to economic burdens concerning termination of pregnancy for women and other patients who are denied access to care. One commenter stated that there is well-documented research that shows the significant healthcare costs women experience when they face healthcare denials. Another commenter stated that women will suffer negative health effects or death if they are denied services relating to complications from an abortion or a miscarriage. Another commenter stated that there are costs to patients facing discrimination as a result of having a previous termination of pregnancy.

Several commenters contended that the proposed rule would place undue costs and burdens on survivors of sexual and domestic violence. The commenters stated that healthcare programs provide critical and costly care for survivors of domestic violence, sexual assault, and human trafficking. The commenters stated that recent data from the CDC shows that the lifetime per-victim cost of intimate partner violence was $103,767 for women victims, with 59% going to medical costs, and that more than 550,000 injuries due to intimate partner violence require medical attention each year.

Response: The Department appreciates comments in this regard. This final rule fully commits the Department to enforcement of Section 1557 and Title IX to protect women from discrimination on the basis of sex, including and especially vulnerable populations such as survivors of domestic violence, sexual assault, and human trafficking. As noted above, court orders have already enjoined and now vacated the termination of pregnancy provisions from the 2016 Rule. Therefore, this final rule does not have a direct material economic impact with regard to discrimination on the basis of termination of pregnancy. This final rule further ensures the Department will enforce Section 1557 and Title IX consistent with the statutory provisions of Title IX. The Department lacks data or methods enabling it to provide quantitative estimates of any alleged economic impacts related to termination of pregnancy provisions.

Comment: A commenter contended that the Department should conduct a cost-benefit analysis specifically on the impact of adopting Title IX's religious exemptions, or compliance with RFRA.

Response: The Department disagrees. The Title IX statute already includes certain exemptions concerning religious groups, and RFRA protects certain exercises of religion from substantial burdens. This final rule affirms that the Department will only enforce Section 1557 consistent with the statutory provisions of Title IX and RFRA, and amends the Title IX regulations to explicitly include the provisions of the Title IX statute concerning religious groups and abortion neutrality. As the Department is already bound by statute to implement Title IX and Section 1557 consistent with those statutes and with RFRA, the Department does not attribute its compliance with those statutes to be attributable to this final rule. Economic impacts due to compliance with Title IX and RFRA would be attributable, not to this final rule, but to those statutes themselves, and are not relevant for this regulatory impact analysis.

Comment: One commenter stated that the Department should estimate the economic impacts of its conforming amendments.

Response: Section 1557 encompasses all the CMS programs addressed by the conforming amendments, so the Department's estimates of impacts of changes to the Section 1557 rule already encompass the impact on entities covered by those rules.

(5) 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 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 final rule 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 final 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 change to its Title IX regulations will

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. This final rule does not subject Title IX funding recipients to new obligations, but rather implements Title IX according to its statutory text, and relieves potential burdens on the States or tribes that could have resulted from any prior interpretation of Title IX by HHS that was inconsistent with the statute. This final rule allows States and tribes to adopt or continue to provide nondiscrimination protections on the basis of sexual orientation, gender identity, or termination of pregnancy, in State, local, and tribal law. Therefore, the Department has determined that this final rule does 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.

Comment: One commenter stated it was inconsistent for the Department to say the 2016 Rule imposed burdens on States but that the proposed rule would not impose new burdens.

Response: The 2016 Rule imposed or may have imposed burdens concerning notices and taglines, as well as gender identity and termination of pregnancy provisions beyond the text of Title IX. This final rule can relieve such burdens without imposing new burdens. To the extent that the gender identity and termination of pregnancy provisions were vacated in October 2019, the Department agrees this final rule does not relieve such burdens, but to the same extent, this final rule does not impose any corresponding burdens.

Comment: A commenter stated that HHS points to no evidence of substantial burdens on States and localities as regards the provision or coverage of medically necessary care related to gender transition.

Response: The Department's conclusion that this final rule does not impose new burdens on States and localities is independent of the Department's suggestion that the 2016 Rule, to the extent it prohibited discrimination on grounds exceeding Title IX and State and local law, also imposed burdens on such States and localities.

Comment: One commenter stated that the proposed rule could impose additional costs on States that adopted policies related to private insurance and Medicaid based on the 2016 Rule that see an increase in healthcare discrimination complaints in their State-level human rights commissions, as HHS OCR will no longer receive such complaints, and such States may reinstate or maintain exclusions and face costly litigation.

Response: The court orders preliminarily enjoining and eventually vacating the 2016 Rule's gender identity and termination of pregnancy provisions have been in effect since December 2016. States have, therefore, not been bound by those provisions, and this final rule's changes in that regard will not cause States to need to change their policies in that regard. States will also not likely see an increase in complaints at the State level as a result of this rule, because HHS OCR has not been able to enforce those provisions for almost the entire lifespan of the 2016 Rule. Finally, this rule does not require States to reinstate exclusions from coverage, so litigation that States might face as a result of doing so are not directly attributable to this final rule.

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 § 6(a)(3)(B).[382] 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 § 2(a). The Department does not believe that the final rule would implicate the requirements of Executive Orders 12866 and 13175 with respect to tribal sovereignty.

(6) 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 § 1(b)(10). Section 1557 itself requires avoidance of duplication by providing that the enforcement mechanisms under specifically identified civil rights laws ''shall apply for purposes of violations'' of Section 1557. 42 U.S.C. 18116(a).[383] The preamble to the 2016 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 at 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 at 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 2016 Rule'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 taglines requirements on health insurance marketplaces, QHP 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.[384]

[382] As stated in the preceding section, the final rule does not have Federalism implications.

[383] 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).

[384] 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 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

Furthermore, a Department of Treasury regulation imposed taglines requirements for hospital organizations to qualify for tax-exempt status.[385] Additionally, in 2003, the Department issued guidance under Title VI, setting forth a flexible four-factor framework to assess the necessity and reasonableness for providing written translation for LEP individuals.[386] Finally, the ACA 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).

Substantially replacing many provisions of the 2016 Rule, 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 final rule is deemed an E.O. 13771 deregulatory action. The Department estimates that this final rule would generate $0.24 billion 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 [ACA] shall exercise all authority and discretion available to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [ACA] 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 ACA, the 2016 Rule imposed significant regulatory burdens on covered entities, including States, healthcare providers, and health insurers, without sufficient corresponding benefits for patients or beneficiaries. By proposing to substantially replace the 2016 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 final rule will particularly reduce the economic burden imposed on healthcare providers and insurers required to provide taglines under the 2016 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 taglines 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 final rule under Executive Order 12866, this rule is expected to be a major rule for purposes of the CRA because it generates cost savings of over $100 million. The Department will comply with the CRA's requirements to inform Congress.

D. Unfunded Mandates Reform Act

This final 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. Public Law 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 rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the 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 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 on revenue for at least five percent of small entities.

Based on its examination, the Department has concluded that this final rule does not have a significant economic impact on a substantial number of small entities. The preamble to the 2016 Rule discussed the character of small entities impacted by the 2016 Rule in detail. 81 FR at 31463–64. Although this final rule will affect numerous small entities, it does not create new or expanded requirements,

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, 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 will no longer apply under this final rule.

[385] *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).

[386] 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).

and, for all the reasons stated in the RIA, it will be reducing economic burdens on such entities overall. The changes concerning gender identity and termination of pregnancy, having already been vacated by court order, are not expected to result in any impact. The changes to the Department's Title IX rule 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. The changes made in conforming amendments overlap those made in the Section 1557 rule and described in the RIA.

To the extent that this final rule imposes economic costs, these are generally limited to entities' voluntary choices to revise their policies and procedures and conduct training, and the Department believes 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 final 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 final 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 final 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 § 1–2(b), 45 FR 72995 (Nov. 2, 1980). The proposed rule was reviewed and approved by the Attorney General, and this final rule was also reviewed and approved by the Attorney General in finalizing the proposed rule without change.

G. Paperwork Reduction Act

The Department has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* Under the rule, 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 has obtained Paperwork Reduction Act approval for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form) [387] separate from this rulemaking.

(D) Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office for Civil Rights (OCR), with authority to re-delegate, enforcement and administration of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116]. This delegation includes the authority to develop and direct implementation of the requirements of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116] as applied to the Department and recipients of the Department's funds. This delegation supersedes the delegation of authority under Section 1557 to the Health Resources and Services Administration (HRSA) on April 21, 2016 in 81 FR 25680 (April 29, 2016).

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, Healthcare, 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, Healthcare, 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, Healthcare 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,

[387] *See* HHS OCR, Assurance of Compliance Portal, *https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf.*

Healthcare, 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 amends 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. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.

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. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

* * * * *

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 through 1688; Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988).

■ 10. Amend § 86.2:

■ a. In paragraph (a), by adding ‘‘, 1687, 1688’’ after ‘‘1686’’; and

■ 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, secs. 506–07), the Helms Amendment (*e.g.,* Continuing Appropriations Act, 2019, Pub. L. 116–6, Div. F, Title 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:

PART 92—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

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Authority: 42 U.S.C. 18116; 5 U.S.C. 301, Pub. L. 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).

Subpart A—General Provisions

§ 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 healthcare 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 healthcare, 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 healthcare.

(d) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 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) 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; or

(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 paragraph (b) of this section, 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 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 on or 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)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) 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 20, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

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