DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 440, 457, and 460

Office of the Secretary

45 CFR Parts 80, 84, 86, 91, 92, 147, 155, and 156

[Docket ID: HHS–OS–2022–0012]

RIN: 0945–AA17

Nondiscrimination in Health Programs and Activities

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

ACTION: Notice of proposed rulemaking; notice of Tribal consultation.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing this proposed rule on Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. The Department is also proposing to revise its interpretation regarding whether Medicare Part B constitutes Federal financial assistance for purposes of civil rights enforcement and to revise nondiscrimination provisions to prohibit discrimination on the basis of sexual orientation and gender identity in regulations issued by the Centers for Medicare & Medicaid Services (CMS) governing Medicaid and the Children's Health Insurance Program (CHIP); Programs of All-Inclusive Care for the Elderly (PACE); health insurance issuers and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees; issuers providing essential health benefits; and qualified health plan issuers.

DATES:

Comments: Submit comments on or before October 3, 2022.

Meeting: Pursuant to Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, the Department of Health and Human Services' Tribal Consultation Policy, and the Department's Plan for Implementing Executive Order 13175, the Office for Civil Rights solicits input by tribal officials as we develop the implementing regulations for Section 1557 of the Affordable Care Act at 45 CFR part 92. The Tribal consultation meeting will be held on August 31, 2022, from 2 p.m. to 4 p.m. Eastern Daylight Time.

ADDRESSES: You may submit comments, identified by RIN Number 0945–AA17, by any of the following methods. Please do not submit duplicate comments.

To participate in the Tribal consultation meeting, you must register in advance at *https://www.zoomgov.com/meeting/register/vJIsfu-rqzksEl2T8gUp_lDrWBqkU0223CY.*

Federal Rulemaking Portal: You may submit electronic comments at *https://www.regulations.gov* by searching for the Docket ID number HHS–OS–2022–0012. Follow the instructions for submitting electronic comments. If you are submitting comments electronically, the Department strongly encourages you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), the Department strongly encourages you to convert the PDF to ''print-to-PDF'' format, or to use some other commonly used searchable text format. Please do not submit the PDF in a scanned format. Using a print-to-PDF format allows the Department to electronically search and copy certain portions of your submissions to assist in the rulemaking process.

Regular, Express, or Overnight Mail: You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: 1557 NPRM (RIN 0945–AA17), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

All comments received by the methods and due date specified above may be posted without change to content to *https://www.regulations.gov,* which may include personal information provided about the commenter, and such posting may occur after the closing of the comment period. However, the Department may redact certain non-substantive content from comments before posting, including threats, hate speech, profanity, graphic images, or individually identifiable information about a third-party individual other than the commenter. In addition, comments or material designated as confidential or not to be disclosed to the public will not be accepted. Comments may be redacted or rejected as described above without notice to the commenter, and the Department will not consider in rulemaking any redacted or rejected content that would not be made available to the public as part of the administrative record.

Because of the large number of public comments normally received on **Federal Register** documents, OCR is not able to provide individual acknowledgments of receipt.

Please allow sufficient time for mailed comments to be received timely in the event of delivery or security delays.

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

Docket: For complete access to background documents or posted comments, go to *https://www.regulations.gov* and search for Docket ID number HHS–OS–2022–0012.

FOR FURTHER INFORMATION CONTACT:

Office for Civil Rights

Dylan Nicole de Kervor, (202) 240–3110 or (800) 537–7697 (TDD), or via email at *1557@hhs.gov,* for matters related to Section 1557.

Centers for Medicare & Medicaid Services

John Giles, (410) 786–5545, for matters related to Medicaid.

Emily King, 410–786–8537, for matters related to CHIP.

Timothy Roe, (410) 786–2006 for matters related to Programs of All-Inclusive Care for the Elderly.

Becca Bucchieri, (301) 492–4341, Agata Pelka, (667) 290–9979, or Leigha Basini, (301) 492–4380, for matters related to 45 CFR 155.120, 155.220, 156.125, 156.200, and 156.1230.

Lindsey Murtagh, (301) 492–4106, for matters related to 45 CFR 147.104.

Hannah Katch, (202) 578–9581, for general questions related to CMS amendments.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: Upon request, the Department will provide an accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed regulations. To schedule an appointment for this type of accommodation or auxiliary aid, please

call (202) 240–3110 or (800) 537–7697 (TDD) for assistance or email *1557@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. Section 1557 Background and Rulemaking

In 2010, Congress passed and the President signed into law the Patient Protection and Affordable Care Act (ACA) [1] to reform the country's health insurance system, making health care more affordable and accessible for tens of millions of persons in the United States. Among other things, the ACA provided health care access to many individuals by increasing coverage options and prohibiting discrimination in health care. Section 1557 of the ACA (Section 1557) is one of the government's most powerful tools to ensure access to and coverage of health care in a nondiscriminatory manner. Except as otherwise provided in Title I of the ACA, Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in a health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance. Section 1557 also prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any program or activity that is administered by an Executive Agency, or any entity established under Title I of the ACA or its amendments. The statute cites Title VI of the Civil Rights Act of 1964 [2] (Title VI), Title IX of the Education Amendments of 1972 [3] (Title IX), the Age Discrimination Act of 1975 [4] (Age Act), and Section 504 of the Rehabilitation Act of 1973 [5] (Section 504) to identify the grounds of discrimination prohibited by Section 1557. The statute further specifies that the enforcement mechanisms provided for and available under Title VI, Title IX, the Age Act, or Section 504 shall apply for purposes of violations of Section 1557.[6] The statute authorizes the Secretary of the U.S. Department of Health and Human Services (HHS or the Department) to promulgate implementing regulations for Section 1557.[7]

Section 1557 was effective upon enactment, and the Department's Office for Civil Rights (OCR) began enforcing the law immediately thereafter while drafting implementing regulations.[8]

1. 2016 Rulemaking

On August 1, 2013, the Department published a Request for Information in the **Federal Register**,[9] followed by issuance of a Notice of Proposed Rulemaking (NPRM) on September 8, 2015 (2015 NPRM).[10] The Department finalized the Section 1557 regulation on

[1] The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010, Public Law 111–152, which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA.''

[2] 42 U.S.C. 2000d *et seq.*

[3] 20 U.S.C. 1681 *et seq.*

[4] 42 U.S.C. 6101 *et seq.*

[5] 29 U.S.C. 794.

[6] 42 U.S.C. 18116(a).

[7] *Id.* 18116(c).

[8] *See, e.g.,* Bulletin, U.S. Dep't of Health & Human Servs., The Brooklyn Hospital Center Implements Non-Discriminatory Practices to Ensure Equal Care for Transgender Patients (July 14, 2015), *https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/statement.pdf; OCR Enforcement under Section 1557 of the Affordable Care Act Sex Discrimination Cases,* U.S. Dep't of Health & Human Servs., *https://www.hhs.gov/civil-rights/for-individuals/section-1557/ocr-enforcement-section-1557-aca-sex-discrimination/index.html* (last updated Aug. 1, 2016); *see also C.P.* v. *Blue Cross Blue Shield,* 536 F. Supp. 3d 791, 796 (W.D. Wash. 2021) (citing *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (stating ''[a] claim of discrimination in violation of Section 1557 does not depend on an HHS rule'' in denying a motion to dismiss a challenge to categorical exclusions for treatment for gender dysphoria in a health insurance plan); *Prescott* v. *Rady Children's Hosp. of San Diego,* 265 F. Supp. 3d 1090, 1098 (S.D. Cal. 2017) (denying defendant hospital's motion to dismiss gender identity discrimination complaint under Section 1557 because Department regulations were not in effect at the time of the alleged discrimination, holding the claim of discrimination was grounded in the plain language of the statute).

[9] 78 FR 46558 (Aug. 1, 2013). Responses are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2013-0007/comments.*

[10] 80 FR 54171 (Sept. 8, 2015). The 2015 NPRM received roughly 2,160 comments, which are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2015-0006/comments.*

May 18, 2016 (2016 Rule).[11] The 2016 Rule applied to all health programs and activities, any part of which received Federal financial assistance, and all health programs and activities administered by the Department or by an entity established under Title I of the ACA. The 2016 Rule included provisions intended to provide, for covered health programs and activities, consistent requirements across all prohibited forms of discrimination including grievance procedures, designated employees to coordinate compliance with the law, and notice requirements. The 2016 Rule included a detailed definition section. The 2016 Rule also required covered entities to provide, in ''significant communications,'' notice and information regarding the availability of language assistance services in the 15 most common languages spoken by limited English proficient[12] (LEP) persons in each state. Additionally, it required covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served in covered entities' health programs and activities. It further prohibited discrimination on the basis of sex, including gender identity; outlined requirements for equal program access on the basis of sex; and explicitly prohibited discrimination in health-related insurance and other health-related coverage, including a ban on categorical exclusions of gender-transition-related care in health insurance coverage and other health-related coverage. At the time, though the Department supported a prohibition on discrimination based on sexual orientation as a matter of policy, the 2016 Rule did not explicitly prohibit discrimination on the basis of sexual orientation because no Federal appellate court had yet concluded that sex-based discrimination included sexual orientation discrimination.[13] Instead, relying on the Supreme Court's opinion in *Price Waterhouse* v. *Hopkins,*[14] the 2016 Rule explained that Section 1557's prohibition of discrimination on the basis of sex included sex discrimination related to an individual's sexual orientation where the evidence established that the discrimination was based on gender stereotypes.[15] The 2016 Rule explicitly exempted covered entities from complying with any requirements that would violate applicable Federal statutory protections for conscience and religious exercise.[16]

The 2016 Rule had an effective date of July 18, 2016, except to the extent that the rule required changes to health insurance or group health plan benefits or benefit design, in which case the 2016 Rule applied on the first day of the first plan year that began on or after January 1, 2017.[17]

The 2016 Rule was challenged under the Administrative Procedure Act[18] (APA) and the Religious Freedom Restoration Act[19] (RFRA). Before the rule went into effect, the United States (U.S.) District Court for the Northern District of Texas, in *Franciscan Alliance* v. *Burwell,* enjoined the Department from enforcing the 2016 Rule's prohibition against discrimination on the basis of gender identity or termination of pregnancy.[20] Subsequently, on October 15, 2019, the same district court vacated the 2016 Rule insofar as the 2016 Rule defined discrimination on the basis of sex to include gender identity and termination of pregnancy.[21] In 2021, the court in *Franciscan Alliance* issued an order enjoining the Department from interpreting or enforcing Section 1557 against the plaintiffs in that case in a manner that would require them to perform or provide insurance coverage for gender transition services or abortion.[22] In *Religious Sisters of Mercy et al.* v. *Becerra et al.,* the court enjoined the Department from enforcing Section 1557 against the plaintiffs in that case in a manner that would require them to perform or provide insurance coverage for gender transition services.[23] Both decisions have been appealed on standing and ripeness grounds, among other things. As of the publication of this NPRM, appeals are pending in the Fifth and Eighth Circuits. More recently, another district court in the District of North Dakota in *Christian Employers Alliance* v. *U.S. Equal Employment Opportunity Commission et al.* enjoined the Department from enforcing Section 1557 against the plaintiffs in that case in a manner that would require them to perform or provide insurance coverage for gender transition services or restrict or compel their speech on gender identity issues.[24]

2. 2020 Rulemaking

On June 14, 2019, the Department published a new Section 1557 Notice of Proposed Rulemaking (2019 NPRM), proposing to rescind large portions of the 2016 Rule.[25] Citing the *Franciscan Alliance* litigation, the 2019 NPRM proposed to rescind the 2016 Rule's definition of ''on the basis of sex,'' and, given ''the likelihood that the Supreme Court [would] be addressing the issue in the near future [in its *Bostock* v. *Clayton County*[26] ruling],'' the preamble to the 2019 NPRM proposed not to include a new definition for ''on the basis of sex.'' However, the preamble to the 2019 NPRM identified examples of other government entities that referred to ''sex'' in ''binary and biological'' terms and suggested that Section 1557's prohibition on sex discrimination may not extend to gender identity discrimination.[27]

The 2019 NPRM also proposed to replace or rescind significant portions of the 2016 Rule in order to ''relieve billions of dollars in undue regulatory burdens,'' and ''eliminate provisions [of the 2016 Rule] that are inconsistent or redundant with pre-existing civil rights statutes.''[28] The most common cost concern raised regarding the 2016 Rule was the notice requirements at former § 92.8, which required covered entities to include a notice of nondiscrimination and notice of the availability of language assistance services (''taglines'') in a range of communications.[29]

In addition, the 2019 NPRM proposed to eliminate the following provisions of the 2016 Rule: the definitions section, including the definition of ''health program or activity'' to include all of the

[11] 81 FR 31375 (May 18, 2016).

[12] In the Proposed Rule at § 92.4, *infra,* a limited English proficient (LEP) individual means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. An LEP individual may be competent in English for certain types of communication (*e.g.,* speaking or understanding), but still be LEP for other purposes (*e.g.,* reading or writing).

[13] 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.'').

[14] 490 U.S. 228, 250–51 (1989).

[15] 81 FR 31389, 31390.

[16] *See* former 45 CFR 92.2(b)(2). ''Insofar as application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.''

[17] 81 FR 313756, 31378, 31430, 31466.

[18] 5 U.S.C. 551 *et seq.*

[19] 42 U.S.C. 2000bb *et seq.*

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

[21] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928 (N.D. Tex. 2019).

[22] *Franciscan All., Inc.* v. *Becerra,* 553 F. Supp. 3d 361 (N.D. Tex. 2021), *amended,* No. 7:16–cv–00108–O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021), *appeal pending,* No. 21–11174 (5th Cir. Nov. 21, 2021).

[23] *Religious Sisters of Mercy* v. *Azar,* 513 F. Supp. 3d 1113 (D.N.D. 2021), *judgment entered sub nom. Religious Sisters of Mercy* v. *Cochran,* No. 3:16–cv–00386, 2021 WL 1574628 (D.N.D. Feb. 19, 2021), *appeal pending,* No. 21–1890 (8th Cir. April 20, 2021) (oral argument held Dec. 15, 2021).

[24] *Christian Emp'rs All.* v. *EEOC,* No. 21–cv–00195, 2022 WL 1573689 (D.N.D. May 16, 2022).

[25] 84 FR 27846 (June 14, 2019).

[26] 140 S. Ct. 1731 (2020).

[27] 84 FR 27853–55, 27856–57.

[28] 84 FR 27848–49.

[29] *See e.g.,* 84 FR 27857–58.

operations of an entity principally engaged in providing or administering health insurance or health-related coverage (former § 92.4); the requirement to designate a responsible employee to carry out a covered entity's responsibilities under Section 1557 (former § 92.7(a)); the requirement to adopt grievance procedures (former § 92.7(b)); notice and tagline requirements (former § 92.8); the approach to accepting disparate impact claims with respect to allegations of sex discrimination (former § 92.101(b)(3)(ii) and (iii)); the requirement for covered entities to justify sex-specific health programs or activities by demonstrating that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective (former § 92.101(b)(3)(iv)); the requirement for a covered entity to take reasonable steps to provide meaningful access to *each* LEP individual (former § 92.201(a)) (emphasis added); the prohibition on discrimination in health-related insurance and other health-related coverage, including a prohibition of blanket exclusions of coverage for care related to gender transition (former § 92.207); the coverage of certain employee health benefit programs (former § 92.208); the prohibition of discrimination on the basis of association (former § 92.209); reference to compensatory damages for Section 1557 violations to the extent such damages are available under underlying Federal civil rights statutes (former § 92.301(b)); and the provision regarding the obligation to provide OCR access to review records and sources of information, and to otherwise comply with the Department's investigations (former § 92.303(c)).

On June 12, 2020, the Department publicly posted its second Section 1557 Final Rule (2020 Rule), making no substantive changes from the 2019 NPRM.[30] On June 15, 2020, the U.S. Supreme Court issued its ruling in *Bostock* v. *Clayton County,* holding that discrimination on the basis of sexual orientation and gender identity constitutes prohibited discrimination because of sex under Title VII of the Civil Rights Act of 1964 (Title VII).[31] The 2020 Rule was published in the **Federal Register** on June 19, 2020 with preamble language that was inconsistent with the Supreme Court's *Bostock* opinion.[32]

Following the issuance of the 2020 Rule, which included an effective date of August 18, 2020,[33] litigants in various U.S. District Courts sought to enjoin the rule on the basis that it was, among other allegations, arbitrary and capricious and contrary to law under the APA.[34] While these challenges addressed a range of changes made to the 2016 Rule, they primarily focused on the 2020 Rule's repeal of the definition of ''on the basis of sex''; the incorporation of provisions governing the 2020 Rule's relationship to other laws related to various religious exemptions; the scope of coverage; and the elimination of language access provisions. As a result of these challenges, the Department is currently preliminarily enjoined from enforcing its repeal of certain portions of the 2016 Rule's definition of ''on the basis of sex,'' and of former 45 CFR 92.206, regarding equal program access on the basis of sex, as well as from enforcing the 2020 Rule's incorporation of Title IX's religious exemption.[35] The five pending lawsuits were stayed for the Department's review of the 2020 Rule.

3. May 10, 2021 Notification of Interpretation (''Bostock Notification'')

On May 10, 2021, the Department publicly announced, consistent with the Supreme Court's decision in *Bostock,* that the Department would interpret Section 1557's prohibition on sex discrimination to include (1) discrimination on the basis of sexual orientation and (2) discrimination on the basis of gender identity (''Bostock Notification'').[36] The Department explained that its interpretation will guide OCR's complaint processing and investigations; however, the interpretation did not ''determine the outcome in any particular case or set of facts.'' In addition, the Department explained that its Section 1557 enforcement will comply with RFRA and all other legal requirements, including applicable court orders that have been issued in litigation involving Section 1557 regulations.

There are currently three court challenges to the Department's Bostock Notification, generally alleging violations of the APA and RFRA.[37] As of this writing, two opinions have been issued: (1) the district court in *Neese* v. *Becerra* denied the defendants' motion to dismiss, finding that the plaintiffs plausibly pled that neither Section 1557 nor *Bostock* prohibit health care providers from discriminating on the basis of sexual orientation and gender identity,[38] and (2) the district court in *Christian Employers Alliance* v. *EEOC* has preliminarily enjoined the Department from interpreting or enforcing Section 1557 and its implementing regulations against plaintiffs in a manner that would require them to provide, offer, perform, facilitate, or refer for gender transition services or that prevents, restricts or compels the plaintiffs' speech on gender identity issues.[39] All three cases remain pending.

4. March 2, 2022 Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy

On March 2, 2022, the Department published guidance, consistent with the Bostock Notification, that Section 1557

[30] 85 FR 37160 (June 19, 2020) (''After considering public comments, in this final rule, the Department revises its Section 1557 regulations . . . as proposed, with minor and primarily technical corrections.''). The 2019 NPRM received roughly 155,960 comments, which are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2019-0007.*

[31] 140 S. Ct. 1731 (2020).

[32] 85 FR 37178–37180.

[33] *Id.* at 37169.

[34] *Walker* v. *Azar,* No. 20–cv–2834 (E.D.N.Y. June 26, 2020); *Whitman-Walker Clinic* v. *U.S. Dep't of Health & Human Servs.,* No. 1:20–cv–01630 (D.D.C. June 22, 2020); *N.Y.* v. *U.S. Dep't of Health & Human Servs.,* No. 1:20–cv–05583 (S.D.N.Y. July 20, 2020); *BAGLY* v. *U.S. Dep't of Health & Human Servs.,* No. 20–cv11297 (D. Mass. July 9, 2021); *Chinatown Serv. Ctr.* v. *U.S. Dep't of Health & Human Servs.,* No. 1:21–cv–00331 (D.D.C. Oct. 13, 2021).

[35] *Walker* v. *Azar,* 480 F. Supp. 3d 417, 430 (E.D.N.Y. 2020) (enjoining repeal of definition of ''on the basis of sex,'' including sex stereotyping); *Whitman-Walker Clinic* v. *U.S. Dep't of Health & Human Servs.,* 485 F. Supp. 3d 1 (D.D.C. 2020) (enjoining repeal of definition of ''on the basis of sex,'' insofar as it includes ''discrimination on the basis of . . . sex stereotyping'' and enjoining incorporation of Title IX religious exemption); *Walker* v. *Azar,* No. 20–cv–2834, 2020 WL 6363970, at *4 (E.D.N.Y. Oct. 29, 2020) (enjoining repeal of former 45 CFR 92.206). The 2020 Rule provides that ''[i]nosofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by'' various statutes including Title IX's religious exemption, ''such application shall not be imposed or required.'' 45 CFR 92.6(b). Relying on language in the 2020 Rule's preamble, the *Whitman-Walker* court preliminarily construed § 92.6(b) to explicitly incorporate Title IX's religious exemption. *Whitman-Walker Clinic,* 485 F. Supp. 3d at 14, 43. These orders did not affect the district court's vacatur of the 2016 Rule insofar as it defined sex discrimination to include gender identity discrimination in *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928 (N.D. Tex. 2019).

[36] 86 FR 27984 (May 25, 2021) (U.S. Dep't of Health & Human Srvs.' Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972). *See also Hammons* v. *Univ. of Md. Med. Sys. Corp.,* 551 F. Supp. 3d 567, 590 (D. Md. 2021) (stating that *Bostock* ''made clear that the position stated in HHS' [Bostock Notification] was already binding law.'').

[37] *Neese* v. *Becerra,* No. 2:21–cv–00163–Z (N.D. Tex. Aug. 25, 2021); *Am. Coll. of Pediatricians* v. *Becerra,* No. 1:21–cv–00195 (E.D. Tenn. Aug. 27, 2021); *Christian Emp'rs All.* v. *EEOC,* No. 21–cv–00195 (D.N.D. Oct. 18, 2021).

[38] No. 2:21–cv–00163–Z, 2022 WL 1265925, at *14 (N.D. Tex. Apr. 26, 2022).

[39] No. 21–cv–00195, 2022 WL 1573689, at *9 (D.N.D. May 16, 2022).

prohibits discrimination on the basis of gender identity in access to covered health programs and activities.[40] Specifically, the Department stated that ''[c]ategorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally funded covered entities restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity likely violates Section 1557.'' [41] On March 31, 2022, the U.S. Department of Justice (DOJ) issued a letter to State Attorneys General addressing protections against unlawful discrimination based on gender identity, including protections afforded by Section 1557.[42]

There is currently one challenge to the Department's gender-affirming care notice alleging violations of the APA.[43] On May 26, 2022, the district court denied Defendants' supplemental motion to dismiss, finding that the March 2, 2022 Notice and Guidance was a final agency action and that Plaintiff had stated a credible threat of enforcement.[44]

B. Summary of the Proposed Rule

The Department proposes to revise the 2020 Rule to reinstate regulatory protections from discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs and activities, consistent with the statutory text of Section 1557 and Congressional intent.

This proposed rule would reflect Section 1557's application to health programs and activities of the Department, which holds the Department accountable to the same standards of compliance with civil rights laws to which it holds recipients of Federal financial assistance. The proposed rule would also reinstate the rule clarifying that Section 1557 generally applies to many health insurance issuers and also prohibits discrimination in health insurance and other health-related coverage,[45] furthering a central goal of the ACA—to increase access to health-related coverage—by ensuring that Section 1557's robust civil rights protections apply to health insurance and other health-related coverage.

The proposed rule also seeks to create consistent procedural requirements for covered health programs and activities by requiring grievance procedures (for employers with 15 or more employees), the designation of a responsible employee (for employers with 15 or more employees), and the affirmative provision of civil rights notices. The absence of such consistency leaves individuals with different procedural protections in covered programs and activities depending on whether their complaint is based on race, color, national origin, sex, age, and/or disability. Further, the Department proposes to require covered entities to have in place a set of policies and procedures to support compliance with Section 1557, and to train relevant staff on their respective policies and procedures. The Department also proposes notice requirements, striking a balance between concerns raised by covered entities in response to the 2016 Rule and the importance of providing the public with information about their civil rights. The rule also proposes to implement robust protections for LEP individuals that ensure each LEP person has meaningful access to covered health programs and activities. The Department also proposes to address nondiscrimination on the basis of sex, including gender identity and sexual orientation, consistent with *Bostock* and related case law, as well as subsequent Federal agency interpretations.[46] Further, the rule proposes to ensure equal program access on the basis of sex and prohibit discrimination on the basis of sex related to marital, family, or parental status. The Department additionally proposes provisions related to nondiscrimination in the use of clinical algorithms in health care decision-making and in telehealth services.

The Department further proposes to apply the provisions applicable to Title VI to administrative enforcement actions against recipients of Federal financial assistance (recipients) and State Exchanges concerning discrimination on the basis of race, color, national origin, sex, and disability, consistent with Section 504 [47] and Title IX [48] regulations. For administrative enforcement actions against recipients and State Exchanges concerning discrimination on the basis of age, the Department proposes to employ the procedural provisions that apply under the Age Act. The Department proposes to apply the federally conducted Section 504 enforcement mechanisms with respect to administrative enforcement actions against the Department, including the Federally-facilitated Exchanges. Additionally, the Department proposes to adopt a process by which recipients may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate Federal conscience or religious freedom laws, so that the Department may, as appropriate, make a determination that recipients are exempt from, or entitled to a modification of the application of, a provision or provisions of this part.

The Department is proposing to revise its position regarding whether Medicare Part B payments constitute Federal financial assistance for purposes of Federal civil rights jurisdiction under Title VI, Section 504, Title IX, the Age Act, and Section 1557. The Department explains that payments made under the Medicare Part B program meet the longstanding definition of ''Federal financial assistance,'' and proposes necessary conforming amendments to the appendices of the implementing regulations for Title VI and Section 504.

Finally, the Department proposes to make limited amendments to the Centers for Medicare & Medicaid Services (CMS) Medicaid, Children's Health Insurance Program (CHIP), and Program of All-Inclusive Care for the Elderly (PACE) nondiscrimination regulatory provisions, as well as nondiscrimination provisions applicable to group and individual health insurance markets and Health Insurance Exchanges to clarify that discrimination on the basis of sex

[40] U.S. Dep't of Health & Human Servs., HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (Mar. 2, 2022), *https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf.*

[41] *Id.* at 2.

[42] Letter from Kristen Clarke, Assistant Att'y Gen., Civil Rights Div., U.S. Dep't of Justice, to State Att'ys Gen. (Mar. 31, 2022), *https://www.justice.gov/opa/press-release/file/1489066/download.*

[43] First Amended Compl., *Tex.* v. *EEOC, et al,* No. 2:21–cv–00194–Z (N.D. Tex. Mar. 9, 2022).

[44] Order, *Tex.* v. *EEOC, et al,* No. 2:21–cv–00194–Z (N.D. Tex. May 26, 2022).

[45] The term ''health coverage'' generally refers to a ''[l]egal entitlement to payment or reimbursement for your health care costs, generally under a contract with a health insurance company, a group health plan offered in connection with employment, or a government program like Medicare, Medicaid, or the Children's Health Insurance Program (CHIP).'' *Glossary: Health coverage, HealthCare.gov, https://www.healthcare.gov/glossary/health-coverage/* (last visited June 15, 2022).

[46] *E.g.,* Memorandum from Pamela S. Karlan, Principal Deputy Assistant Att'y Gen., to Fed. Agency Civil Rights Dirs. & Gen. Counsels (Mar. 26, 2021) [hereinafter Karlan Memo], *https://www.justice.gov/crt/page/file/1383026/download;* 86 FR 32637 (June 22, 2021) (U.S. Dep't of Educ., notice of interpretation).

[47] 45 CFR 84.61 (adopting the procedural provision of Title VI).

[48] *Id.* § 86.71 (adopting the procedural provision of Title VI).

includes discrimination on the basis of sexual orientation and gender identity.

II. Reasons for the Proposed Rulemaking

The Department is undertaking this rulemaking to better align the Section 1557 regulation with the statutory text of 42 U.S.C. 18116, to reflect recent developments in civil rights case law, to address unnecessary confusion in compliance and enforcement resulting from the 2020 Rule, and to better address issues of discrimination that contribute to negative health interactions and outcomes. Upon further consideration and informed by civil rights issues raised in the context of the coronavirus disease 2019 (COVID–19) pandemic, the Department believes that the 2020 Rule creates substantial obstacles to the Department's ability to address discrimination across the health programs and activities it financially supports or administers, thereby undermining the statutory purpose of Section 1557 and hindering the Department's mission of pursuing health equity and protecting public health.

In developing this NPRM, the Department undertook a significant review of previous rulemaking and developments in civil rights law since the publication of both the 2016 and 2020 Final Rules. The Department also engaged in a series of listening sessions with a diverse range of stakeholder groups.[49]

A. The Scope of the 2020 Rule Is Not the Best Reading of the Affordable Care Act and Section 1557's Statutory Text

In the Department's view, the scope of application in the 2020 Rule is not the best reading of the statutory text of Section 1557 in two significant respects. First, the 2020 Rule applies to ''any program or activity administered by the Department under Title I of the [ACA].'' [50] However, the statutory language provides that Section 1557's discrimination prohibitions apply to covered programs and activities that are ''administered by an Executive Agency *or* any entity established under this title.'' [51] The operative word, ''or,'' distinguishes programs and activities operated by an Executive Agency from those operated by a Title I entity. The 2020 Rule, however, construes this language to cover only programs and activities administered by the Department *under Title I of the ACA,* and programs and activities administered by any entity established under Title I of the ACA.[52] The reading of the statute in the 2020 Rule is strained, and the Department does not believe that the best way to resolve any ambiguity is to construe the phrase ''established under this title'' as modifying the phrase ''administered by an Executive Agency.'' The preamble to the 2020 Rule explained that its construction was ''at least as reasonable'' as the 2016 Rule's resolution of this issue.[53] However, upon further analysis the Department now believes that the reading proposed herein, which does not limit application to only programs and activities administered by the Department under Title I of the ACA, better reflects the statutory language as well as Congress' intent.[54]

Second, the 2020 Rule limits Section 1557's application to health insurance by providing that ''for purposes of this part, an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing health care.'' [55] The statutory text of Section 1557 demonstrates Congress' intent to apply Section 1557 to health insurance. In the description of Federal financial assistance subject to Section 1557, the statute identifies three examples of Federal financial assistance, all of which pertain to health insurance: ''credits, subsidies, or contracts of insurance.'' It is logical to conclude that the inclusion of credits and subsidies in Section 1557's statutory language refers to the tax credits and cost-sharing subsidies provided for under the same title of the ACA (Title I) to assist people in purchasing health insurance coverage. Additionally, as is discussed in detail in this preamble, in enacting the ACA, Congress demonstrated a clear intent to protect individuals from discrimination in health insurance and other health-related coverage. As a general matter, the fact that Section 1557 is contained within the ACA—a law that predominantly regulates health insurance—indicates that Congress intended Section 1557 to apply to health insurance. Thus, the Department, upon further evaluation, believes the 2020 Rule limits application to health insurance and other health-related coverage in a manner inconsistent with the statute and Congressional intent.

B. The 2020 Rule's Preamble Does Not Reflect Recent Developments in Sex Discrimination Law

The 2020 Rule declined to adopt a definition of ''on the basis of sex,'' but the 2019 NPRM and the preamble to the 2020 Rule suggested that Section 1557's prohibition on sex discrimination may not extend to gender identity discrimination.[56] The Supreme Court has now held that Title VII's prohibition of employment discrimination on the basis of sex encompasses discrimination based on sexual orientation and gender identity.[57] The Court reasoned that, even if Congress understood that ''the term 'sex' in 1964 referred to 'status as either male or female [as] determined by reproductive biology,' '' Title VII prohibits discrimination based on sexual orientation and gender identity.[58] Since *Bostock,* two Federal courts of appeals have held that the plain language of Title IX's prohibition on sex discrimination must be read similarly.[59] The DOJ has also taken this position in Title IX litigation.[60]

On January 20, 2021, President Biden, in Executive Order (E.O.) 13988, directed agencies to review all agency actions, including regulations, that prohibit discrimination on the basis of sex to determine if they were inconsistent with the Court's reasoning in *Bostock*.[61] In response, the Department assessed its Section 1557 regulation and enforcement policies and issued its Bostock Notification. As discussed previously, the Bostock Notification stated that the Department would interpret and enforce Section 1557's sex discrimination prohibitions

[49] A list of stakeholder groups and notes from these listening sessions and written materials provided during or after the listening sessions are attached to the docket of this proposed rule as a supplemental material at *federalregister.gov.*

[50] 45 CFR 92.3(a)(2).

[51] 42 U.S.C. 18116(a) (emphasis added).

[52] 45 CFR 92.3(a)(2)–(3) (emphasis added).

[53] 85 FR 37160, 37170 (June 19, 2020).

[54] *See, e.g., Griffin* v. *Breckenridge,* 403 U.S. 88, 97 (1971) (civil rights statutes should be construed broadly); *U.S.* v. *Price,* 383 U.S. 787, 801 (1966) (same); *see also N. Haven Bd. of Educ.* v. *Bell,* 456 U.S. 512, 521 (1982) (''[I]f we are to give Title IX the scope that its origins dictate, we must accord it a sweep as broad as its language.''); S. Rep. No. 64, 100th Cong., 2d Sess. 5–7 (1988), reprinted in 1988 U.S.C.C.A.N. 3, 7–9 (statement of Sen. Humphrey stating that Title VI should be interpreted as broadly as necessary to eradicate discriminatory practices in programs that Federal funds supported).

[55] 45 CFR 92.3(c).

[56] 84 FR 27846, 27853–55, 27856–57 (June 14, 2019); 85 FR 37178–79.

[57] *Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731 (2020).

[58] *Id.* at 1739–40, 1743.

[59] See *Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878 (Mem) (2020).

[60] *See, e.g.,* U.S. Dep't of Justice, En Banc Brief as Amicus of the United States, *Adams* v. *Sch. Bd. of St. Johns Cty.,* No. 18–13592, 22 (11th Cir. Nov. 26, 2021); U.S. Dep't of Justice, Statement of Interest of the United States, *B.P.J.* v. *W. Va. Bd. of Educ.,* No. 2:21–cv–00316 (S.D.W. Va. June 17, 2021).

[61] 86 FR 7023, 7023–24 (Jan. 25, 2021).

consistent with *Bostock,* while recognizing that the interpretation did not ''determine the outcome in any particular case or set of facts'' and that the Department would comply with RFRA and all other legal requirements.[62] For these reasons and those described in this NPRM, the Department believes the understanding of sex discrimination described in the 2020 Rule's preamble [63] is an inaccurate reading of the statute.

The 2020 Rule's preamble relied heavily on the 2016 injunction and 2019 vacatur issued by the district court in the *Franciscan Alliance* case, which predated the *Bostock* decision, when removing the 2016 Rule's gender identity provisions.[64] The district court in that case found that Section 1557's prohibition of sex discrimination did not cover gender identity discrimination.[65] Even prior to *Bostock,* a number of courts had reached a contrary conclusion and held that Federal sex discrimination protections, including Section 1557, provided protection to transgender and gender-nonconforming individuals, although the exact rationales used by these courts varied.[66] Notably, the *Bostock* Court presumed for the sake of argument that ''sex'' referred only to ''biological distinctions between male and female'' and still found that Title VII's prohibition of sex discrimination prohibits discrimination on the basis of sexual orientation and gender identity.[67] Following *Bostock,* courts have continued to hold that Federal sex discrimination protections, including Section 1557 and Title IX, cover gender identity discrimination.[68] While some post-*Bostock* decisions have placed limits on Section 1557's application to discrimination against transgender people, these decisions have focused on whether RFRA exempts specific entities from potential future enforcement by HHS of Section 1557's requirements against them; for the most part they do not call into question *Bostock*'s application to Section 1557.[69] In its Bostock Notification, the Department affirmed its commitment to complying with RFRA and all other legal requirements supporting religious exercise and freedom of conscience while also affirming Section 1557's prohibition of discrimination on the basis of gender identity and sexual orientation.[70]

C. The 2020 Rule Causes Unnecessary Confusion in Compliance

The 2020 Rule provides no guidance on how covered entities are to implement their compliance responsibilities under Section 1557 and, in particular, whether those responsibilities are the same as, or deviate from, their compliance responsibilities under Title VI, Title IX, Section 504, and the Age Act. Rather, it generally states the nondiscrimination requirements of Section 1557 by restating the statutory language of 42 U.S.C. 18116(a), followed by stating that the grounds prohibited are the grounds found in the Title VI, Title IX, Section 504, and Age Act statutes.[71] The resulting uncertainty is particularly stark for procedural requirements—including the designation of a responsible employee, the provision of notices of nondiscrimination, and adoption of grievance procedures—as the 2020 Rule removed the 2016 Rule provisions addressing these issues.

The implementing regulations for the statutes referenced in Section 1557 require covered entities to have different policies and procedures depending on the alleged basis of discrimination. For example, only the regulations promulgated under Section 504 [72] and Title IX [73] require recipients to implement grievance procedures; regulations to implement Title VI and the Age Act specify no such regulatory requirement. Given that the 2020 Rule does not reference grievance procedures, covered entities are unsure of their responsibility to have a grievance procedure for handling complaints of discrimination in their health programs and activities. As such, it would be reasonable for a covered entity to believe that the 2020 Rule does not require such a procedure. However, a covered entity could also reasonably believe that it must have a grievance procedure to address allegations of disability and sex discrimination, as this is what is independently required under Section 504 and Title IX regulations, but not for complaints of race, color, national origin, or age discrimination because neither the Title VI nor Age Act regulations have such a requirement. To further complicate the issues, the requirement to have a grievance procedure under Section 504 is limited to covered entities that employ 15 or more people, whereas the Title IX regulation requires grievance procedures for covered entities regardless of the number of employees.

As this discussion illustrates, the approach in the 2020 Rule has caused confusion in compliance by failing to provide clear procedural requirements. The 2020 Rule also significantly pared down regulatory language related to the specific discriminatory actions prohibited that one generally finds in an

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[62] 86 FR 27984; *see also* Karlan Memo, *supra* note 46.

[63] 85 FR 37160, 37178–79 (June 19, 2020).

[64] 85 FR 37163–65 (citing *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016) and *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928 (N.D. Tex. 2019)).

[65] *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d at 688.

[66] *See, e.g., Whitaker By Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017) (Title IX); *Smith* v. *City of Salem, Ohio,* 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa* v. *Park W. Bank & Trust Co.,* 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schroer* v. *Billington,* 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Boyden* v. *Conlin,* 341 F. Supp. 3d 979 (W.D. Wis. 2018) (Section 1557 and Title VII); *Flack* v. *Wis. Dep't. of Health Servs.,* 395 F. Supp 3d 1001, 1014 (W.D. Wis. 2019) (Section 1557 and Equal Protection Clause); *Prescott* v. *Rady Children's Hosp. San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (Section 1557); *Tovar* v. *Essential Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (Section 1557).

[67] *Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731, 1739 (2020).

[68] *Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878 (Mem) (2020); *Kadel* v. *Folwell,* No. 1:19–cv–00272, 2022 WL 2106270, at *28–*29 (M.D.N.C. June 10, 2022); *Scott* v. *St. Louis Univ. Hosp.,* No. 4:21–cv–01270–AGF, 2022 WL 1211092, at *6 (E.D. Mo. Apr. 25, 2022); *C.P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–cv–06145–RJB, 2021 WL 1758896, at *4 (W.D. Wash. May 4, 2021); *Koenke* v. *Saint Joseph's Univ.,* No. CV 19–4731, 2021 WL 75778, at *2 (E.D. Pa. Jan. 8, 2021); *Doe* v. *Univ. of Scranton,* No. 3:19–cv–01486, 2020 WL 5993766, at *11 n.61 (M.D. Pa. Oct. 9, 2020); *Maxon* v. *Seminary,* No. 2:19–cv–9969, 2020 WL 6305460 (C.D. Cal. Oct. 7, 2020); *B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 2:21–cv–00316, 2021 WL 3081883, at *7 (S.D.W. Va. July 21, 2021); *Clark Cty. Sch. Dist.* v. *Bryan,* 478 P.3d 344, 354 (Nev. 2020).

[69] *Franciscan All., Inc.* v. *Becerra,* No. 7:16–cv–00108–O, 2021 WL 3492338 (N.D. Tex. Aug. 9, 2021), *as amended* (Aug. 16, 2021), *appeal pending,* No. 21–11174 (5th Cir. Nov. 21, 2021); *Religious Sisters of Mercy* v. *Azar,* 513 F. Supp. 3d 1113 (D.N.D. 2021), *judgment entered sub nom. Religious Sisters of Mercy* v. *Cochran,* No. 3:16–cv–00386, 2021 WL 1574628 (D.N.D. Feb. 19, 2021), *appeal pending,* No. 21–1890 (8th Cir. April 20, 2021) (oral argument held Dec. 15, 2021); *but see Neese* v. *Becerra,* No. 2:21–cv–00163–Z, 2022 WL 1265925, at *14 (N.D. Tex. Apr. 26, 2022) (denying motion to dismiss based on possibility that neither Section 1557 nor *Bostock* prohibit health care providers from discriminating on the basis of sexual orientation and gender identity).

[70] 86 FR 27984. Three Federal district courts have enjoined the Department from enforcing Section 1557 in certain respects against the plaintiffs in those cases and their members. *See Religious Sisters of Mercy,* 513 F. Supp. at 1153–54; *Franciscan All., Inc.* v. *Becerra,* 553 F. Supp. 3d 361, 378 (N.D. Tex. 2021), *amended,* No. 7:16–CV–00108–O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021); *Christian Emp'rs All.* v. *EEOC,* No. 21–cv–00195, 2022 WL 1573689 (D.N.D. May 16, 2022). The Department has appealed the injunctions in *Religious Sisters of Mercy* and *Franciscan Alliance,* and those appeals remain pending. The Department is currently abiding by those injunctions and will continue to do so after this Rule takes effect, to the extent those injunctions remain in place.

[71] 45 CFR 92.2.

[72] *Id.* § 84.7(b).

[73] *Id.* § 86.8(b).

implementing regulation for a civil rights statute.[74] The Department believes covered entities and protected individuals need additional clarity regarding the specific discriminatory actions prohibited under Section 1557, including clarification regarding whether and how those actions found in the implementing regulations of the statutes referenced in Section 1557 may also apply.

D. Proposed Changes Are Consistent With the Statute and Will Further the Intended Purpose of the Statute

Despite the best efforts of many health care professionals, inequities in access to health care resulting in disparities in health status and outcomes persist. Such disparities pose a major public health challenge for the United States and hinder efforts by health care professionals who work to ensure that their patients receive quality care. As discussed throughout this preamble, discrimination in health care can contribute to these disparities, which negatively impacts communities of color, individuals with disabilities, women, lesbian, gay, bisexual, transgender,[75] queer, and intersex [76] (LGBTQI+) [77] individuals, LEP individuals, and older adults and children. Critically, access to health care that is free from discrimination benefits *all* communities and people, and is also vital to addressing public health emergencies, such as the COVID–19 pandemic. For example, ensuring nondiscriminatory access to health care, vaccines, and protective equipment during a public health emergency will more effectively and expeditiously end the emergency for everyone.[78]

Strong civil rights protections play a significant role in advancing an equitable society, and every part of government must contribute to ensuring that people in the United States enjoy the protections guaranteed to them. Since taking office, President Biden has issued more than a dozen directives aimed at promoting equity, including the robust enforcement of civil rights.[79] Discrimination in health programs and activities can lead to disparate health outcomes and adverse differences in access to care.[80] Accordingly, the Department is committed to doing its part to eliminate such discrimination, including through robust implementation and enforcement of Section 1557. Moreover, the Department is committed to addressing different, intersecting forms of discrimination experienced by individuals who may be entitled to protection from discrimination on more than one of the protected bases under Section 1557 and whose experience of discrimination may be both quantitatively and qualitatively different from that of individuals experiencing single-basis discrimination.

1. Health Equity and Discrimination Related to Race, Color, and National Origin

Members of racial and ethnic groups that have historically faced discrimination and structural disadvantages in the United States experience disproportionately poor health status.[81] Though health indicators for aggregated racial and ethnic populations may suggest positive outcomes for some groups, broad demographic categories often conceal health disparities within and among racial and ethnic subgroups. For example, positive overall data on the health of persons of Asian descent often obscure disparities among subgroups.[82] One study revealed that while Asian persons in the aggregate appeared to be healthier than white persons in the United States, disaggregation of the data shows that persons of Filipino descent experience a higher prevalence of fair or poor health, obesity, high blood pressure, diabetes, or asthma when compared with white persons.[83] Similarly, while the rate of low birth weight infants is lower for the total Hispanic/Latino population in the United States in comparison to non-Hispanic white people, Puerto Ricans have a low birth weight rate that is almost twice that of non-Hispanic white people.[84]

Beyond poor health outcomes, communities of color in the United States have long experienced disparities in health care—including in health insurance coverage, access to care, quality of care, maternal mortality rates, and inclusion in biomedical research. For example, American Indian/Alaska Native, Black, and Hispanic/Latino adults account for a disproportionately high share of the uninsured population. American Indian/Alaska Native individuals under 65 have an uninsured rate of 28 percent, higher than any other racial or ethnic group.[85] Hispanic/Latino people comprise 29 percent of the uninsured yet make up 19 percent of the U.S. population.[86] These

[74] For example, the implementing regulations for each of Section 1557's referenced statutes include provisions describing specific actions that constitute prohibited discrimination. *See* 45 CFR 80.3 (Title VI) § 84.4 (504); § 86.31 (Title IX); and § 91.11 (Age Act). Consistent with these implementing regulations, the 2016 Rule included a comparable provision at former 45 CFR 92.101, which the 2020 Rule repealed and purportedly replaced with § 92.2, which does not identify specific, prohibited discriminatory actions. *See* 85 FR 37160, 37200 (June 19, 2020); 45 CFR 92.2.

[75] When used in this preamble, the term ''transgender'' refers to people who identify as a gender other than their sex assigned at birth. This may include people who identify as nonbinary, genderqueer, or gender nonconforming, regardless of whether those individuals explicitly use the term transgender to describe themselves.

[76] When used in this preamble, the term ''intersex'' refers to people born with variations in physical sex characteristics—including genitals, gonads, chromosomes, and hormonal factors—that do not fit typical binary definitions of male or female bodies.

[77] We use ''+'' in this acronym to indicate inclusion of individuals who may not identify with the listed terms but who have a different identity with regards to their sexual orientation, gender identity, or sex characteristics.

[78] *See, e.g.,* Ann Lee & Sheila David, *Ensuring Equitable Access to Vaccines,* Stan. Soc. Innovation Rev., Jun. 29, 2021, *https://ssir.org/articles/entry/ensuring_equitable_access_to_vaccines#.*

[79] *See, e.g.,* E.O. 13985, 86 FR 7009 (2021); E.O. 13988, 86 FR 7023 (2021); E.O. 13995, 86 FR 7193 (2021); Memorandum on Redressing Our Nation's and the Federal Government's History of Discriminatory Housing Practices and Policies (2021), *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-redressing-our-nations-and-the-federal-governments-history-of-discriminatory-housing-practices-and-policies/;* Memorandum on Condemning and Combating Racism, Xenophobia, and Intolerance Against Asian Americans and Pacific Islanders in the United States (2021), *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-condemning-and-combating-racism-xenophobia-and-intolerance-against-asian-americans-and-pacific-islanders-in-the-united-states/;* E.O. 14012, 86 FR 8722 (2021); E.O.14031, 86 FR 29675 (2021); E.O. 14035, 86 FR 34593 (2021); E.O. 14041, 86 FR 50443 (2021); E.O.14045, 86 FR 51581 (2021); and other Presidential Actions.

[80] 156 Cong. Rec. S1842 (daily ed. Mar. 23, 2010), *https://www.congress.gov/congressional-record/2010/03/23/senate-section/article/S1821-6.*

[81] U.S. Dep't of Health & Human Servs., Office of Minority Health, Minority Population Profiles, *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=26* (last visited Nov. 9, 2021).

[82] Alexander Adia et al., *Health Conditions, Outcomes, and Service Access Among Filipino, Vietnamese, Chinese, Japanese, and Korean Adults in California,* 2011–2017, 110 a.m. J. of Pub. Health 520 (2020), *https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2019.305523.*

[83] *Id.*

[84] U.S. Dep't of Health & Human Servs., Office of Minority Health, Profile: Hispanic/Latino Americans *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=64* (last visited Nov. 19, 2021).

[85] The U.S. Census does not classify the Indian Health Service as health coverage. U.S. Dep't of Health & Human Servs., Assistant Sec'y for Policy & Evaluation, Office of Health Policy, Issue Brief: Health Insurance Coverage and Access to Care for American Indians and Alaska Natives: Current Trends and Key Challenges, p. 1 (July 22, 2021), *aspe-aian-health-insurance-coverage-ib.pdf* (*hhs.gov*).

[86] U.S. Dep't of Health & Human Servs., Assistant Sec'y for Policy & Evaluation, Office of Health Policy, Issue Brief: The Remaining Uninsured: Geographic and Demographic Variation, p. 1 (Mar. 23, 2021), *https://aspe.hhs.gov/sites/default/files/*

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disparities are particularly salient in states that did not expand Medicaid; 37 percent of the total uninsured Black population in the United States reside in just three such states.[87]

In addition to experiencing disparities in coverage, people of color are also more likely than white people to experience a lower quality of care. For example, HHS' 2021 National Health Care Quality and Disparities Report evaluated whether different racial groups received worse care than white individuals in the areas of patient safety, person-centered care, care coordination, the effectiveness of care, healthy living, and affordable care. The study found that Black individuals received worse care than white individuals for 43 percent of 195 quality measures, American Indian/Alaska Native individuals received worse care than white individuals for 40 percent of 108 quality measures, Hispanic/Latino individuals received worse care than white individuals for 36 percent of 172 quality measures, Native Hawaiian/Pacific Islander individuals reported receiving a lower level of care than white people for 28 percent of 81 quality measures, and where Asian individuals received worse care than white individuals, it was for 28 percent of 173 quality measures.[88] While many factors may contribute to these disparities, the report highlights the role of social determinants of health,[89] which include racial and ethnic discrimination, limited English proficiency, and presence of health care laws.[90]

Further, the disparities in maternal mortality rates are alarming. According to National Vital Statistics System data, in 2020, the maternal mortality rate for non-Hispanic/Latino Black women was 55.3 deaths per 100,000 live births, 2.9 times the rate for non-Hispanic/Latino white women (19.1).[91] This disparity is increasing, with maternal mortality rate increases between 2019 and 2020 for non-Hispanic/Latino Black and Hispanic/Latino people.[92] An analysis of vital statistics mortality data showing the cause of maternal deaths in the United States from 2016–2017 revealed maternal mortality for Black women largely resulted from conditions like preeclampsia and cardiomyopathy, and were believed to be preventable.[93] This study also found an increased risk of maternal mortality from multiple causes in Black women, which indicates negative impacts of structural racism on health and health care in the United States. The Biden-Harris Administration has taken initial steps to address these longstanding disparities, issuing the first-ever Presidential proclamation observing Black Maternal Health Week [94] and hosting the first-ever Federal ''Maternal Health Day of Action,'' which included a nationwide call to action to reduce mortality. The Administration has also announced several key policy actions, including CMS' intention to propose the first-ever hospital quality designation specifically focused on maternity care.[95]

While research is beginning to reveal more information about the potential causes of Black maternal mortality, less research exists about the causes of maternal mortality among American Indian/Alaska Native women. A recent study documented the available literature on American Indian/Alaska Native women and found that the three leading causes of maternal mortality among such women are hemorrhage, cardiomyopathies, and hypertensive disorders of pregnancy.[96] The authors ultimately concluded that more research is needed to determine the root causes of maternal mortality among American Indian/Alaska Native women, but suggested that to reduce American Indian/Alaska Native maternal mortality and eliminate racial/ethnic disparities, provider-related factors including implicit bias must be addressed.[97]

Persistent bias and racism in the health care system, as well as across other social determinants of health, also contribute to health challenges for people of color. For example, one study showed that medical students and medical residents hold false beliefs about biological differences between Black people and white people, and these falsely held beliefs are associated with racial disparities in pain perception and treatment recommendation accuracy.[98] A recent study analyzing patients' electronic health records (EHR) found that Black patients had disproportionately higher odds of being described with one or more negative descriptors in the history and notes of the EHR than their white counterparts.[99] The authors note that this may indicate implicit racial bias against Black patients, potentially leading to stigmatizing Black patients and compromising the care they receive. A recent survey indicates that, shaped by these experiences and perceptions, most Black adults believe that racial discrimination is not uncommon in health care.[100] Black adults, and Black women in particular, are more likely than white people to report certain negative health care experiences.[101] Racism and discrimination experienced outside the health care setting may also affect the mental and physical well-being of individuals of color. For example, Black people who experience

private/pdf/265286/Uninsured-Population-Issue-Brief.pdf.

[87] *Id.* at p. 8.

[88] U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, 2021 National Healthcare Quality and Disparities Report Executive Summary, pp. ES–3, D–3–D–51 (Dec. 2020), *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2021qdr.pdf.*

[89] Social determinants of health are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. *Social Determinants of Health,* Healthy People 2030, U.S. Dep't of Health & Human Servs., Office of Disease Prevention & Health Promotion, *https://health.gov/healthypeople/objectives-and-data/social-determinants-health* (last visited January 21, 2022).

[90] U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, 2019 National Healthcare Quality and Disparities Report Executive Summary, p. 7 (Dec. 2020), *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2019qdr-final-es-cs061721.pdf.*

[91] Donna L. Hoyert, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, Maternal Mortality Rates in the United States (Feb. 2022), *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf.*

[92] *Id.*

[93] Marian F. MacDorman et al., *Racial and Ethnic Disparities in Maternal Mortality in the United States Using Enhanced Vital Records, 2016–2017,* 111 a.m. J. Pub. Health 1673, 1671 (2021), *https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306375.*

[94] The White House Briefing Room, A Proclamation on Black Maternal Health Week, 2021 (April 13, 2021), *www.whitehouse.gov/briefing-room/presidential-actions/2021/04/13/a-proclamation-on-black-maternal-health-week-2021/ ;see also,* The White House Briefing Room, A Proclamation on Black Maternal Health Week, 2022 (April 8, 2022), *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/08/a-proclamation-on-black-maternal-health-week-2022/ .*

[95] The White House Briefing Room, FACT SHEET: Biden-Harris Administration Announces Initial Actions to Address the Black Maternal Health Crisis (Apr. 13, 2021), *www.whitehouse.gov/briefing-room/statements-releases/2021/04/13/fact-sheet-biden-harris-administration-announces-initial-actions-to-address-the-black-maternal-health-crisis./*

[96] Jennifer L. Heck et al., *Maternal Mortality Among American Indian/Alaska Native Women: A Scoping Review.* 30 J. of Women's Health 220, 229 (2021), *https://www.liebertpub.com/doi/epdf/10.1089/jwh.2020.8890.*

[97] *Id.* at 226.

[98] Kelly M. Hoffman et al., *Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites,* 113 Proc. of the Nat'l Acad. of Sci. 4296, 4301 (2016), *https://doi.org/10.1073/pnas.1516047113.*

[99] Michael Sun et al., *Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record,* 41 Health Affairs 203, 211 (2022), *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.01423.*

[100] Liz Hamel et al., The Kaiser Family Found., The Undefeated Survey on Race and Health, p. 4 (2020), *https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf.*

[101] *Id.* at 5.

racism were more likely to experience deteriorations in health that contribute to premature death, including increased risk of inflammation and chronic illness.[102]

It is well-documented that LEP people experience obstacles to accessing health care in the United States.[103] Language barriers negatively affect LEP patients' ability to comprehend their diagnoses and understand medical instructions when they are delivered in English, and impact their comfort with post-discharge care regimens.[104] For example, Hispanic/Latino LEP people report worse access to care and report the receipt of fewer preventive services than Hispanic/Latino people who speak English proficiently.[105] For Asian Americans who are not proficient in English, language barriers are one of the most significant challenges to accessing health care, including making an appointment, communicating with health care professionals, and gaining knowledge about an illness.[106] This is even more pronounced among older Asian Americans, who are more likely to have limited English proficiency.[107] Studies show that LEP patients experience longer hospital stays—leading to a greater risk of line infections, surgical infections, falls, and pressure ulcers—when compared to English-speaking patients.[108] Because LEP patients have greater difficulty understanding medical instructions when those instructions are given in English, they are at higher risk of surgical delays and readmissions.[109] Although the use of qualified interpreters is effective in improving care for LEP patients, some clinicians choose not to use them, fail to use them effectively, or rely instead on ad hoc interpreters—such as family members or untrained bilingual staff.[110] However, in addition to posing legal and ethical concerns, ad hoc interpreters are more likely to make mistakes than professional interpreters.[111] Also, clinicians with basic or intermediate non-English spoken language skills often attempt to communicate with the patient on their own without using an interpreter, increasing patient risk.[112] These barriers contribute to disparities in health outcomes for LEP individuals, which have likely worsened during the COVID–19 pandemic.[113]

2. Health Equity and Discrimination Related to Sex

Disparities in women's health are well-documented. For example, although heart disease is the leading cause of death for men and women in the United States, women are more likely to experience delays in emergency care and treatment to control their cholesterol levels.[114] Women are also more likely than men to die from a heart attack.[115] The delay in the diagnosis and treatment of heart disease is just one of many disparities women experience in health care settings. Some evidence suggests that women treated by male physicians for heart attacks experience higher rates of mortality compared to women treated by a female physician or by a male physician who has had more exposure to female patients and female physicians.[116]

Studies regarding pain management have also indicated the risk of gender bias, based on the notion that men and women are ''separate and different in manners and needs,'' with a review of the literature revealing studies that show women receive less adequate pain medication, more antidepressants, and more mental health referrals compared to men.[117] Studies indicate this may have to do with erroneous gender stereotypes that men are ''stoic, in control, and avoid[] seeking health care,'' whereas women are presented as ''more sensitive to pain and more willing to show and to report pain'' compared to men.[118]

LGBTQI+ individuals in the United States also face pervasive health disparities and barriers in accessing needed health care. Throughout this preamble, we will use the full acronym of LGBTQI+ when talking broadly about individuals who are LGBTQI+ but will use a subset of the acronym (*e.g.,* ''LGB,'' ''LGBT'' or ''LGBTQ'') when discussing studies, research, or concepts that apply only to a subset of this group.

Overall, LGBTQI+ individuals report being in poorer health than non-LGBTQI+ individuals. LGBTQ+ individuals, moreover, are at increased risk for or are particularly affected by certain health conditions, including sexually transmitted infections,[119] Human Immunodeficiency Virus (HIV),[120] obesity,[121] conditions associated with tobacco, alcohol, and other substance use,[122] and mental

[102] Jamila Taylor, The Century Found., Racism, Inequality, and Health Care for African Americans, p. 6 (2019), *https://production-tcf.imgix.net/app/uploads/2019/12/19172443/AfAmHealth_Jamila_PDF.pdf.*

[103] Jason Espinoza et al., *How Should Clinicians Respond to Language Barriers that Exacerbate Health Inequity?,* 23 a.m. Med. Ass'n J. of Ethics E109 (2021) (LEP patients and families in the U.S. ''face barriers to health service access, experience lower quality care, and suffer worse health outcomes''), *https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021–02/cscm3–2102.pdf.*

[104] *Id.; see also* Leah S. Karliner et al., *Convenient Access to Professional Interpreters in the Hospital Decreases Readmission Rates and Estimated Hospital Expenditures for Patients with Limited English Proficiency,* 55 Med. Care 199 (2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5309198/.*

[105] Espinoza, *supra* note 103.

[106] Wooksoo Kim et al., *Barriers to Healthcare Among Asian Americans,* 25 Soc. Work in Pub. Health 286, 289 (2010), *https://www.tandfonline.com/doi/pdf/10.1080/19371910903240704?needAccess=true.*

[107] *Id.*

[108] U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, Executive Summary: Improving Patient Safety Systems for Patients with Limited English Proficiency (Sept. 2020), *https://www.ahrq.gov/health-literacy/professional-training/lepguide/exec-summary.html#what.*

[109] *Id.*

[110] Espinoza, *supra* note 103, at 110.

[111] *See, e.g.,* Glenn Flores et al., *Errors of Medical Interpretation and Their Potential Clinical Consequences: A Comparison of Professional Versus Ad Hoc Versus No Interpreters,* 5 Annals of Emerg. Med. 545 (Nov. 1, 2012), *https://pubmed.ncbi.nlm.nih.gov/22424655/*; Ali Labaf et al., *The Effect of Language Barrier and Non-Professional Interpreters on the Accuracy of Patient-Physician Communication in Emergency Department,* 3 Adv. J. Emerg. Med., June 6, 2019, at p. 4, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6789075/pdf/AJEM-3-e38.pdf.*

[112] U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, *supra* note 108.

[113] *See* Lala Tanmoy Das et al., *Addressing Barriers to Care for Patients with Limited English Proficiency During the COVID–19 Pandemic,* Health Affairs Blog (July 29, 2020), *https://www.healthaffairs.org/do/10.1377/hblog20200724.76821/full/.*

[114] *What Health Issues or Conditions Affect Women Differently than Men?,* U.S. Dep't of Health & Human Servs., Nat'l Inst. of Child Health & Human Dev., *https://www.nichd.nih.gov/health/topics/womenshealth/conditioninfo/howconditionsaffect* (last visited Mar. 15, 2022).

[115] Brad Greenwood et al., *Patient-Physician Gender Concordance and Increased Mortality Among Female Heart Attack Patients,* 115 Proc. Nat'l Acad. Sci. 8569, 8574 (2018), *https://www.pnas.org/doi/epdf/10.1073/pnas.1800097115.*

[116] *Id.*

[117] Anke Samulowitz 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 Res. & Mgmt., Feb. 25, 2018, at pp. 1, 9–10, *https://downloads.hindawi.com/journals/prm/2018/6358624.pdf*; *see also* Danielle M. Wesolowicz et al., *The Roles of Gender and Profession on Gender Role Expectations of Pain in Health Care Professionals,* 11 J. of Pain Res. 1121 (2018), *https://www.dovepress.com/getfile.php?fileID=42642.*

[118] Samulowitz, *supra* note 117, at pp. 1, 9.

[119] Hilary Daniel et al., Annals of Internal Med. Position Papers, Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper from the American College of Physicians (2015), *https://www.acpjournals.org/doi/full/10.7326/M14-2482?journalCode=aim.*

[120] U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, HIV Surveillance Report, 2019; Vol. 32, pp. 19, 24, 46 (2021), *https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-32.pdf.*

[121] Daniel, *supra* note 119.

[122] *Id.*

health conditions,[123] including suicidality.[124] LGB people are more likely to acquire a disability at a younger age than heterosexual individuals.[125]

Discrimination also poses a major challenge to the health of LGBTQI+ people. A 2018 literature review revealed that 82 percent of studies found ''robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people.'' [126] Anti-LGBT discrimination is associated with a higher risk of poor mental and physical health, including depression, anxiety, post-traumatic stress disorder, substance use, and cardiovascular disease.[127] These effects are exacerbated for youth and people of color who identify as LGBT.[128] Significant proportions of LGBTQ people report negative experiences with doctors and other health care providers.[129] According to a recent survey, negative experiences with providers occur at higher rates among transgender people, particularly transgender people of color, than among other LGBTQ subgroups.[130]

With respect to transgender individuals, the Department believes that it is particularly important to acknowledge that evidence demonstrates that some health care providers have discriminated against and continue to discriminate against transgender people based on their gender identities. Transgender people commonly report that their providers asked them unnecessarily invasive questions about their gender identity; were physically or verbally abusive; refused them gender-affirming care; or refused to see them at all due to their gender identity.[131] In some cases, transgender people and their providers face discriminatory obstacles at the hospitals or health systems where those providers work or have admitting privileges.[132] Fear of disrespect and discrimination leads many LGBTQI+ people to report delaying or forgoing needed health care, especially for those who identify as transgender.[133] While there is less published research addressing discrimination and disparate health outcomes in individuals with intersex conditions, preliminary studies suggest many of the same concerns and disparities apply.[134]

LGBTQI+ people also face barriers to obtaining health insurance, which can impact their access to appropriate health care. Insured rates for LGB+ people have risen substantially since the implementation of the ACA coverage expansions, yet research indicates that some of these gains in coverage were lost between 2016 and 2019.[135] Although research suggests that transgender people have benefited from the ACA's coverage expansions and consumer protections,[136] significant disparities persist in the uninsured rate for transgender people when compared to cisgender [137] people. Nearly one in five transgender adults reported that they lacked insurance from 2017–2018.[138] Furthermore, transgender people who can access insurance may nonetheless be denied coverage for needed services, including gender-affirming care.[139] For example, more than 40 percent of transgender respondents in one survey said their health insurance company denied them coverage for a gender-affirming surgery; a similar proportion reported that they were denied coverage for hormone therapy.[140]

Recent research confirms that the COVID–19 pandemic has also exacerbated the health disparities identified above for LGBTQI+ people. Specifically, LGBTQ+ people, who have a higher prevalence of underlying health conditions, are more susceptible to COVID-related illnesses and death.[141] Another study revealed that LGBT+ people, in general, have experienced increased negative mental health impacts during the COVID–19 pandemic compared with non-LGBT+ people.[142] LGBTQ+ youth, in particular, may have experienced increased negative mental health impacts during the pandemic based on increased feelings of isolation and the inability to access supportive community groups and LGBTQ+ friendly spaces resulting from stay-at-home orders and social distancing

[123] Charlotte Patterson et al., Nat'l Acads. of Sci., Eng'g, & Med., Understanding the Well-Being of LGBTQI+ Populations, p. 298 (2020), *https://doi.org/10.17226/25877*.

[124] Daniel, *supra* note 119.

[125] *Id.*

[126] What We Know Project, Cornell U., What Does the Scholarly Research Say About the Effects of Discrimination on the Health of LGBT People (2019), *https://whatweknow.inequality.cornell.edu/wp-content/uploads/2019/12/LGBT-Discrimination-Printable-Findings-121319.pdf*.

[127] *Lesbian, Gay, Bisexual, and Transgender Health, HealthyPeople.gov, https://healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health* (last visited June 8, 2022).

[128] *Id.; see also* Bianca D.M. Wilson et al., The Williams Inst., UCLA Sch. of Law, Racial Differences Among LGBT Adults in the US: LGBT Well-Being at the Intersection of Race (2022), *https://williamsinstitute.law.ucla.edu/wp-content/uploads/LGBT-Race-Comparison-Jan-2022.pdf*.

[129] Sharita Gruberg et al., Ctr. for Am. Progress, The State of the LGBTQ Community in 2020 (2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/*.

[130] Sandy E. James et al., Nat'l Ctr. for Transgender Equality, The Report of the 2015 U.S. Transgender Survey, p. 97 (2016), *https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf*.

[131] *Id.* at pp. 96–97.

[132] *See, e.g.,* Chico Harlan, *A Small-Town Doctor Wanted to Perform Surgeries for Transgender Women. He Faced an Uphill Battle,* Wash. Post (Nov. 11, 2017), *https://www.washingtonpost.com/national/a-small-town-doctor-wanted-to-perform-surgeries-for-transgender-women-he-faced-an-uphill-battle/2017/11/11/c6073a0a-c3d7-11e7-84bc-5e285c7f4512_story.html*.

[133] Patterson, *supra* note 123, at p. 292.

[134] Laetitia Zeeman & Kay Aranda, *A Systematic Review of the Health and Healthcare Inequalities for People with Intersex Variance,* 17 Int'l J. of Envtl. Res. & Pub. Health 6533 (2020), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7559554/*; Amy Rosenwohl-Mack et al., *A National Study on the Physical and Mental Health of Intersex Adults in the U.S.,* 15 PLoS ONE, Oct. 9, 2020, *https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0240088*.

[135] U.S. Dep't of Health & Human Servs., Assistant Sec'y for Policy & Evaluation, Office of Health Policy, Issue Brief: Health Insurance Coverage and Access to Care for LGBTQ+ Individuals: Current Trends and Key Challenges, p. 4 (June 2021), *https://aspe.hhs.gov/sites/default/files/2021-07/lgbt-health-ib.pdf*.

[136] Gruberg, *supra* note 129.

[137] The term ''cisgender'' refers to a person whose gender identity is the same as the person's assigned sex at birth.

[138] Wyatt Koma et al., The Kaiser Family Found., Demographics, Insurance Coverage, and Access to Care Among Transgender Adults (2020), *https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/*.

[139] For purposes of this preamble, the term ''gender-affirming care'' refers to care for transgender individuals (including those who identify using other terms, for example, nonbinary or gender nonconforming) that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition. Gender-affirming care may also be, but is not necessarily, referred to as ''gender-affirming health services'' or ''transition-related care.'' The terms ''gender-affirming care'' or ''transition-related care'' also include care sought by individuals with intersex conditions who seek treatment for gender dysphoria. *See* World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, pp. 68–71 (7th Version 2012) [hereinafter WPATH Standards], *https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341* (last visited Feb. 7, 2022).

[140] Gruberg, *supra* note 129.

[141] Dustin Nowaskie & Anna Roesler, *The Impact of COVID–19 on the LGBTQ+ Community: Comparisons Between Cisgender, Heterosexual People, Cisgender Sexual Minority People, and Gender Minority People,* 309 Elsevier Psychiatry Res., Jan. 10, 2022, at pp. 1, 3, *www.sciencedirect.com/science/article/pii/S0165178122000051*.

[142] Lindsey Dawson et al., Kaiser Family Found., The Impact of the COVID–19 Pandemic on LGBT+ People's Mental Health (2021), *https://www.kff.org/other/issue-brief/the-impact-of-the-covid-19-pandemic-on-lgbt-peoples-mental-health/#:~:text=LGBT%20people%20reported%20the%20COVID,rates%20than%20non%2DLGBT%20people*.

recommendations.[143] These youth may also face familial rejection and related mental health and other consequences.[144] Compared to non-LGBT+ people, larger shares of LGBT+ people reported COVID-related employment disruptions.[145] Thus, accessing and affording mental health care [146] and health insurance generally [147] during the pandemic is disproportionally more difficult for LGBT+ people compared to their numbers in the general population.

3. Health Equity and Discrimination Related to Age

Although the health disparities discussed above exist in all age groups, older adults experience unique age-related discrimination that negatively impacts their health. There is evidence that age discrimination has negative effects on the physical and mental health of older adults,[148] including fatigue, pain, cognitive impairment, depression, and anxiety.[149] Older adults have reported discrimination including providers disregarding their knowledge of their own health care needs, having their pain ignored for prolonged periods of time, and providers assuming that as older adults they are cognitively compromised or unable to communicate their medical concerns.[150] Some older adults also report being disrespected, rushed, and ignored by their health care providers.[151] One study on age discrimination found that one in 17 adults over the age of 50 experience frequent age discrimination in health care settings, and this is associated with a new or worsened disability within four years.[152]

Health care disparities for older adults were tragically amplified by the impact of COVID–19. Recent data show that individuals 65 and older account for 74.3 percent of COVID–19 deaths in the United States.[153] Older adults in nursing homes in particular faced far worse outcomes. Older adults who require a nursing home level of care account for only about 2 percent of the Medicare population but represented about 22 percent of all COVID–19 cases from March 2020 through December 2020.[154] Across all demographic breakdowns, nursing home beneficiaries of Medicare had much higher rates of COVID–19 than beneficiaries in the community, with Hispanic/Latino, Black, and Asian American nursing home beneficiaries having the highest rates.[155] Similarly, nursing home residents were 12 times more likely to be hospitalized with COVID–19 [156] and 43 percent died within 30 days of hospitalization as compared to 22 percent of the individuals admitted from the community.[157] Thus, older adults in nursing homes were dying at higher rates than the general population and disproportionate to their numbers in the general population. Studies suggest that longstanding concerns associated with institutionalization such as crowding, understaffing, and facilities with fewer resources and oversight contributed to the devastating COVID–19 health disparities for older adults in nursing homes.[158]

Older adults of color sometimes experience discrimination in health care settings because of their age and their race. A recent study found that one in four Black and Hispanic/Latino adults in the U.S. age 60 and older reported that they have been treated unfairly or have felt that their health concerns were not taken seriously by health professionals because of their racial or ethnic background.[159] The findings from the report also stated that more than a quarter of U.S. older adults said they did not get the care or treatment they believed they needed,[160] and U.S. older adults who have experienced discrimination in a health care setting were more likely to have worse health status, face economic hardships, and be more dissatisfied with their care than those who did not experience discrimination.[161]

Additionally, even though life expectancy and overall health have improved in recent years for most older Americans, with the exception of what we have seen during the COVID–19 pandemic where older Americans have been disproportionately negatively impacted, not all older adults are benefitting equally because of factors such as race, gender, and disability. For example, it is expected Hispanic/Latino and Black people will experience the largest increases in Alzheimer's disease and related dementias between 2015 and 2060.[162] Additionally, women are nearly two times more likely to be affected by Alzheimer's disease than men.[163] A recent survey commissioned by the Alzheimer's Association found that the ability to obtain a diagnosis, manage the disease, and access care and support services for dementia vary widely depending on race, ethnicity, geography, and socioeconomic status.[164] These disparities reach beyond clinical care to include uneven representation of Black, Hispanic/Latino, Asian American and American Indian/Alaska Native populations in Alzheimer's research and clinical trials as well.[165]

[143] Ishaan Sachdeva et al., *Letter to the Editor: The Disparities Faced by the LGBTQ+ Community in Times of COVID–19,* 297 Elsevier Psychiatry Res., Jan. 14, 2021, *https://www.sciencedirect.com/science/article/pii/S0165178121000226*; Laurie A. Drabble & Michael J. Eliason, *Introduction to Special Issue: Impacts of the COVID–19 Pandemic on LGBTQ+ Health and Well-Being,* 68 J. Homosexuality 545, 549 (2021), *https://www.tandfonline.com/doi/pdf/10.1080/00918369.2020.1868182?needAccess=true*; Scott Emory Moore et al., *Disproportionate Impact of the COVID–19 Pandemic on Perceived Social Support, Mental Health and Somatic Symptoms in Sexual and Gender Minority Populations,* 68 J. Homosexuality 577, 587 (2021), *www.tandfonline.com/doi/full/10.1080/00918369.2020.1868184.*

[144] Sachdeva, *supra* note 143.

[145] Dawson, *supra* note 142.

[146] Nowaskie, *supra* note 141, at p. 3; *see also* Brad Sears et al., Williams Inst., UCLA Sch. of L., The Impact of the Fall 2020 COVID–19 Surge on LGBT Adults in the U.S., p. 10 (2021), *https://williamsinstitute.law.ucla.edu/wp-content/uploads/COVID-LGBT-Fall-Surge-Feb-2021.pdf.*

[147] Drabble, *supra* note 143, at 548.

[148] David Burnes et al., *Interventions to Reduce Ageism Against Older Adults: A Systematic Review and Meta-Analysis,* 109 Am. J. of Pub. Health, e1, e9 (2019), *https://doi.org/10.2105/AJPH.2019.305123.*

[149] *Why Ageism in Health Care Is a Growing Concern,* RegisCollege.edu, *https://online.regiscollege.edu/blog/why-ageism-in-health-care-is-a-growing-concern/* (last visited Apr. 20, 2022).

[150] Judith Graham, '*They Treat Me Like I'm Old and Stupid': Seniors Decry Health Providers' Age Bias,* Kaiser Health News (Oct. 20, 2021), *https://khn.org/news/article/ageism-health-care-seniors-decry-bias-inappropriate-treatment/.*

[151] *Id.*

[152] Stephanie E. Rogers et al., *Discrimination in Healthcare Settings is Associated with Disability in Older Adults: Health and Retirement Study, 2008–2012,* 30 J. Gen. Intern. Med., 1413, 1420 (2015), *https://doi.org/10.1007/s11606–015–3233–6.*

[153] U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, COVID–19 Mortality Overview, Provisional Death Counts for Coronavirus Disease 2019, *https://www.cdc.gov/nchs/covid19/mortality-overview.htm* (last visited Feb. 16, 2022).

[154] U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., The Impact of COVID–19 on Medicare Beneficiaries in Nursing Homes, *https://www.cms.gov/medicare-covid-19-nursing-home-analysis* (last visited Mar. 15, 2022).

[155] *Id.*

[156] *Id.*

[157] *Id.*

[158] *See, e.g.,* Fangli Geng et al., *Daily Nursing Home Staffing Levels Highly Variable, Often Below CMS Expectations,* 38 Health Affairs 1095, 1099 (2019), *https://doi.org/10.1377/hlthaff.2018.05322.*

[159] Michelle M. Doty et al., Commonwealth Fund, How Discrimination in Health Care Affects Older Americans, and What Health Systems and Providers Can Do (2022), *https://doi.org/10.26099/yffm-2x15.*

[160] *Id.*

[161] *Id.*

[162] *Minorities and Women Are at Greater Risk for Alzheimer's Disease,* U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, *https://www.cdc.gov/aging/publications/features/Alz-Greater-Risk.html* (last visited Mar. 15, 2022).

[163] *Id.*

[164] Alzheimer's Ass'n, Special Report: Race, Ethnicity and Alzheimer's in America, p. 72 (2021), *https://www.alz.org/media/Documents/alzheimers-facts-and-figures-special-report.pdf.*

[165] *Id.*

Another age group disadvantaged by health disparities is children. Social determinants of health such as racism and poverty have been shown to have profoundly negative effects on the health status of children and adolescents. Research on the relationship between the impact of racism and the biological effects of chronic exposure to stress hormones at the cellular level reveals links between birth disparities and mental health challenges in youth.[166]

Additionally, the relationship between health disparities and the ability of low-income populations to access safe, healthy homes is well-documented. As early as 2005, the Office of the U.S. Surgeon General reported that 14 percent of low-income renters lived in homes with severe to moderate structural problems including water leaks and mold growth triggering allergic reactions and asthma attacks in residents.[167] Exposure to lead in water sources and paint, soil, and dust particles are known to cause neurological disorders and increased risks of learning and intellectual disabilities in children.[168] Data from national health surveys reveal that children of color, low-income families, and certain geographic regions are disproportionately impacted by lead poisoning.[169] Specifically, Black children are the most likely to have higher blood lead levels, children living in poverty are more likely to have lead in their bodies than other children (regardless of their race/ethnicity or age of the home), and the Southern region of the United States has the highest number of children with lead exposure.[170]

4. Health Equity and Discrimination Related to Disability

Individuals with disabilities face barriers to accessing health care and fare worse on a broad range of health indicators than the general population.[171] In addition to experiencing disparate health outcomes and disparate social determinants of health, individuals with disabilities experience challenges in getting the health care they need. For example, standard medical diagnostic equipment is often inaccessible to individuals with mobility-related disabilities. As a result, as many as 20 million adults in the United States who have a disability that limits their functional mobility may experience challenges accessing preventive, primary, and specialty care due to the lack of accessible medical diagnostic equipment.[172] Lack of physical access may lead to poor quality of care, ''delayed and incomplete care, missed diagnoses, exacerbation of the original disability, and increases in the likelihood of the development of secondary conditions.'' [173]

Disability-based bias and discrimination in the health care setting likely contribute to access issues faced by individuals with disabilities. A recent survey of U.S. physicians' perceptions of individuals with disabilities shows the prevalence of potentially biased views. For example, 82.4 percent of respondents in a study published in 2021 reported that individuals with significant disabilities have worse quality of life than those without disabilities, and only 40.7 percent were very confident about their ability to provide the same quality of care to patients with disabilities.[174] Other studies confirm that some health care providers are likely to deny needed medical care to individuals with disabilities, substitute their own judgment for the preferences of patients with disabilities, and exhibit other forms of implicit and explicit bias.[175]

Compared to individuals without disabilities, people with disabilities are more likely to have unmet medical, dental, and prescription medication needs—especially women with disabilities and individuals with disabilities who have lower incomes.[176] Individuals with disabilities are also less likely to receive preventive health care services, such as routine teeth cleanings and cancer screenings.[177] One study of Medicare beneficiaries with disabilities found that they were significantly more likely to report difficulty accessing care and more likely to lack annual clinician evaluation and management visits for primary and specialty care than those without disabilities.[178] The same beneficiaries were also more likely to have general, nonemergent, and preventable emergency department visits.[179] Female Medicare beneficiaries with disabilities aged 65 and older were found less likely to receive mammography screening

[166] Maria Trent et al., *The Impact of Racism on Child and Adolescent Health,* 144 Am. Acad. of Pediatrics, Aug. 1, 2019, *https://publications.aap.org/pediatrics/article/144/2/e20191765/38466/The-Impact-of-Racism-on-Child-and-Adolescent*.

[167] U.S. Dep't of Health & Human Servs., Office of the Surgeon Gen., The Surgeon General's Call to Action to Promote Healthy Homes (2009), *https://www.ncbi.nlm.nih.gov/books/NBK44192/pdf/Bookshelf_NBK44192.pdf*.

[168] *Health Effects of Lead Exposure,* U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, *https://www.cdc.gov/nceh/lead/prevention/health-effects.htm* (last visited Mar. 15, 2022).

[169] *See, e.g.,* Eric M. Roberts et al., *Assessing Child Lead Poisoning Case Ascertainment in the US, 1999–2010,* 139 Pediatrics, May 2017, *https://publications.aap.org/pediatrics/article/139/5/e20164266/38761/Assessing-Child-Lead-Poisoning-Case-Ascertainment*; *Who is Vulnerable to Childhood Lead Poisoning,* Tracking California, *https://www.trackingcalifornia.org/childhood-lead-poisoning/who-is-vulnerable-to-childhood-lead-poisoning* (last visited Mar. 15, 2022).

[170] *See, e.g.,* Roberts, *supra* note 169; *Who is Vulnerable to Childhood Lead Poisoning, supra* note 169.

[171] *See, e.g.,* Valerie L. Forman-Hoffman et al., *Disability Status, Mortality, and Leading Causes of Death in the United States Community Population,* 53 Med Care 346 (2015), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5302214/*; Gloria L. Krahn et al., *Persons with Disabilities as an Unrecognized Health Disparity Population,* 205 Am. J. Pub. Health S198 (Apr. 2015), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355692/*; *2020 Topics and Objectives: Disability and Health, HealthyPeople.gov, https://www.healthypeople.gov/2020/topics-objectives/topic/disability-and-health* (last visited Nov. 10, 2021); Elham Mahmoudi & Michelle Meade, *Disparities in Access to Health Care Among Adults with Physical Disabilities: Analysis of a Representative National Sample for a Ten-Year Period,* 8 Disability Health J. 182 (2015), *https://pubmed.ncbi.nlm.nih.gov/25263459/*.

[172] Debra L. Brucker & Andrew J. Houtenville, *People with Disabilities in the United States,* 96 Archives of Physical Medicine and Rehabilitation 771 (2015), *https://doi.org/10.1016/j.apmr.2015.02.024*.

[173] Nat'l Council on Disability, Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities, p. 7 (2021), *https://ncd.gov/sites/default/files/Documents/NCD_Medical_Equipment_Report_508.pdf*.

[174] Lisa I. Iezzoni et al., *Physicians' Perceptions of People with Disability and Their Health Care,* 40 Health Affairs 297 (2021), *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01452*. *See also,* Lisa I. Iezzoni et al., *US Physicians' Knowledge About the Americans with Disabilities Act and Accommodation of Patients with Disability,* 41 Health Affairs 96 (2022), *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01136*.

[175] Kenneth A. Gerhart et al., *Quality of Life Following Spinal Cord Injury: Knowledge of Attitudes of Emergency Care Providers,* 24 Annals of Emergency Med. 807 (1994), *https://www.annemergmed.com/article/S0196-0644(94)70318-3/fulltext*; David Carlson et al., Nat'l Disability Rights Network, Devaluing People with Disabilities: Medical Procedures that Violate Civil Rights, pp. 17, 23, 28, 42–43, 49, 54 (2012), *https://www.ndrn.org/wp-content/uploads/2012/05/Devaluing-People-with-Disabilities.pdf*; Laura VanPuymbrouck et al., *Explicit and Implicit Disability Attitudes of Healthcare Providers,* 65 Rehab. Psychology 101 (2020), *https://pubmed.ncbi.nlm.nih.gov/32105109/*.

[176] Andrés J. Gallegos, *Misperceptions of People with Disabilities Lead to Low-Quality Care: How Policy Makers Can Counter that Harm and Injustice,* Health Affairs Blog (Apr. 1, 2021), *https://www.healthaffairs.org/do/10.1377/hblog20210325.480382/full/*.

[177] *2020 Topics and Objectives: Disability and Health, HealthyPeople.gov, https://www.healthypeople.gov/2020/topics-objectives/topic/disability-and-health* (last visited Nov. 10, 2021).

[178] Kenton J. Johnson et al., *Ambulatory Care Access and Emergency Department Use for Medicare Beneficiaries With and Without Disabilities,* 40 Health Affairs 910 (2021), *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01891*.

[179] *Id.*

compared to female beneficiaries of the same age reporting no disability.[180]

A recent study examined the intersectionality of disability and pregnancy and how this may impact risk for maternal morbidity and mortality, thereby underscoring the importance of ensuring nondiscrimination against women with disabilities.[181]

The COVID–19 pandemic exacerbated existing health disparities and uniquely affected individuals with disabilities, who are more likely to have pre-existing health conditions and face barriers to accessing health care, placing them at increased risk of COVID–19 infection and death.[182] Further, some people who have been infected with COVID–19 continue to experience symptoms that can last months after first being infected, or may have new or recurring symptoms at a later time, a condition known as ''long COVID'' that itself can constitute a disability.[183] During the course of the COVID–19 pandemic, OCR has received a number of complaints from aging and disability rights advocates raising concerns that resource allocation decisions under state Crisis Standards of Care were being made in a manner that was discriminatory on the basis of age and disability. OCR provided technical assistance to a number of states to prevent resource allocation decisions from being made on the basis of discriminatory criteria.[184]

5. Improving the Nation's Health Through Civil Rights Protections

The Department is committed to doing its part to address health disparities and to promote equity in health care access through a range of initiatives, including through implementation and enforcement of Section 1557's protections. As reviewed above, the 2016 Rule provided clarity regarding Section 1557's strong statutory protections from discrimination and equipped the Department with the means to enforce these protections. The 2020 Rule, by contrast, limited the Rule's scope, removed principal provisions from the Section 1557 regulation, and left ambiguity regarding the extent of various protections. The 2020 Rule removed specific provisions implementing nondiscrimination protections regarding gender identity. The 2020 Rule also eliminated specific provisions addressing discrimination in health insurance coverage benefit design and eliminated provisions designed to ensure access to language assistance services for LEP individuals. Furthermore, 2020 Rule also narrowed the regulation's application to some, but not all, operations of health insurance issuers and to only certain programs administered by the Department.

The 2020 Rule's removal of specific nondiscrimination provisions from the Section 1557 regulation—including the provision implementing protections based on gender identity discrimination, as well as other changes that could be read to limit the reach of Section 1557—has the potential to increase the incidence of discrimination for groups protected under the statute. As described above, discrimination leads to negative impacts on access to care and mental and physical health outcomes. An increase in discrimination will widen existing disparities and harm the well-being of underserved and historically marginalized individuals and communities. The Department acknowledges the potential interest that covered entities and other stakeholders may have in maintaining the 2020 Rule and recognizes that some of the proposed revisions reflect changes to certain positions articulated in that Rule. However, the Department is also cognizant of the fact that absent revisions to the 2020 Rule, protected groups likely will be relegated to inferior health care access without strong civil rights protections at a moment when health disparities have been magnified by the unequal burden of the COVID–19 pandemic.

III. Nondiscrimination in Health Programs and Activities

Subpart A—General Provisions

Purpose and effective date (§ 92.1)

Proposed § 92.1(a) states that the purpose of this part is to implement Section 1557, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, or Section 504. As discussed further in the Preamble's discussion of proposed § 92.2, HHS interprets Section 1557's prohibition of discrimination on the ''ground[s] prohibited'' under Title VI, Title IX, Age Act, or Section 504 to mean that Section 1557 prohibits discrimination based on race, color, national origin, sex, age, or disability.[185] In addition to incorporating the ''ground[s] prohibited'' by these other statutes, Section 1557 incorporates the ''enforcement mechanisms'' of the statutes.[186] Though the Section 1557 rule is informed by the Title VI, Title IX, Age Act, and Section 504 implementing regulations, Section 1557 provides an independent basis for regulation of discrimination in covered health programs and activities that is distinct from Title VI, Title IX, the Age Act, and Section 504. Section 1557's nondiscrimination requirements do not in any way limit or impact the interpretation of those statutes.[187]

Section 92.1(b) proposes that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of a final rule in the **Federal Register**. This section provides an exception to the start date for provisions of this part that require changes to health insurance or group health plan benefit design. Such provisions will have a delayed implementation date of the first day of the first plan year (in the individual market, policy year) beginning on or after the year immediately following the effective date of the Final Rule in the **Federal Register**. This delayed implementation will allow covered entities to revise their health insurance coverage or other health-related coverage to comply with the regulation and to avoid administrative challenges associated with applying the Final Rule's requirements in the middle of a plan year or policy year. We seek

[180] U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Medicare Current Beneficiary Survey (2013), *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-ADA–2017.pdf*.

[181] Caroline Signore et al., *The Intersection of Disability and Pregnancy: Risks for Maternal Morbidity and Mortality.* 30 J. of Women's Health 147, 153 (2021), *https://doi.org/10.1089/jwh.2020.8864*.

[182] Sabrina Epstein et al., *New Obstacles and Widening Gaps: A Qualitative Study of the Effects of the COVID–19 Pandemic on U.S. Adults with Disabilities,* 14 Disability & Health J. 101103 (2021), *https://doi.org/10.1016/j.dhjo.2021.101103*.

[183] U.S. Dep't of Health & Human Servs. & U.S. Dep't of Justice, Guidance on ''Long Covid'' as a Disability Under the ADA, Section 504, and Section 1557 (July 26, 2022), *https://www.hhs.gov/about/news/2021/07/26/hhs-doj-issue-guidance-on-long-covid-and-disability-rights.html*.

[184] *Civil Rights and COVID–19,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html* (last updated July 26, 2021); Bulletin, U.S. Dep't of Health & Human Servs., Office for Civil Rights, *Civil Rights, HIPAA, and the Coronavirus Disease 2019* (Mar. 28, 2020), *https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf*.

[185] *See Schmitt* v. *Kaiser Found. Health Plan of Wash.,* 965 F.3d 945, 953 (9th Cir. 2020) (''Section 1557(a) incorporates only the prohibited 'grounds' and 'the mechanisms provided for and available under' the four civil rights statutes. A prohibited 'ground' for discrimination . . . is simply the protected classification at issue.'').

[186] 42 U.S.C. 18116(a).

[187] *See id.* 18116(b).

comments from issuers, employers, and other plan sponsors on how long they anticipate it would take to adjust their plan offerings, and from Exchanges on how long they would need to implement the proposed requirements.

Application (§ 92.2)

Proposed § 92.2 addresses the application of this regulation. The Department proposes in § 92.2(a) to apply the rule, except as otherwise provided in this part, to: (1) every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department; (2) every health program or activity administered by the Department; and (3) every program or activity administered by a Title I entity.

Paragraph (a)(1) proposes to make the rule applicable to every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department.

In paragraph (a)(2), we propose to apply the rule to all health programs and activities of the Department. This is consistent with the 2016 Rule, and in contrast to the 2020 Rule, which only applies to those programs and activities administered by the Department under Title I of the ACA. The statute prohibits discrimination on the enumerated bases in ''any program or activity that is administered by an Executive Agency *or* any entity established under this title.'' [188] The operative word, ''or,'' distinguishes programs and activities operated by an Executive Agency from those operated by a Title I entity. Although the 2020 Rule construes this language to cover only programs and activities administered by the Department under Title I of the ACA and programs and activities administered by any entity established under Title I of the ACA, upon further review the Department finds this reading of the statute unpersuasive. We do not believe that the best way to resolve any perceived ambiguity is to construe the phrase ''established under this title'' as modifying the phrase ''administered by an Executive Agency.''

We propose, consistent with the 2016 Rule, to reinstate the word ''health'' to modify ''programs or activities'' operated by the Department. The Department considered applying the rule to all programs and activities of the Department; however, we believe this is an appropriate limitation for this regulation given the specificity of the vast majority of the regulatory provisions to health programs and activities. We seek comment on the implications of this scope; the implications of applying a Section 1557 implementing regulation broadly to all programs and activities of the Department; and, if the Department were to do so, if that should be done through a separate regulation, similar to the Department's Section 504 implementing regulation that applies to programs and activities conducted by the Department at 45 CFR part 85.

Consistent with the 2016 Rule, the Department proposes to limit the application of this rulemaking to the health programs and activities of only the Department itself and not all Executive Agencies. The Department remains committed to working with other Departments that administer health programs and activities to support them in their efforts to ensure that their programs are nondiscriminatory, because Section 1557 applies to programs and activities that are administered by all Executive Agencies.[189] This proposed regulation, however, is limited to HHS.

Proposed paragraph (a)(3) states that the rule applies to every program or activity administered by a Title I entity. Title I entities include State Exchanges (including those on the Federal platform) and federally-facilitated Exchanges, both of which were created under Title I of the ACA.[190] We do not believe the modifier ''health'' is necessary when describing covered programs and activities of Title I entities because they are, as a whole, health programs or activities under the definition of ''health program or activity'' at proposed § 92.4.

Proposed paragraph (b) provides that provisions of this part do not apply to an employer with regard to its employment practices, including the provision of employee health benefits. This is distinct from both the 2016 and 2020 Rules, each of which applied to employment in very limited circumstances. The 2016 Rule did not apply to hiring, firing, promotions, or terms and conditions of employment but did address employee health benefit programs at former § 92.208. This provision was repealed by the 2020 Rule as ''duplicative of, inconsistent with, or confusing in relation to the Department's preexisting regulations,'' which instead reverted to enforcing the statutorily referenced nondiscrimination statutes through their existing regulations.[191]

The Department has considered this issue, in consultation with Federal agencies primarily charged with enforcing existing employment discrimination laws, and is proposing that this part not apply to employment. OCR recognizes that over 55 percent of the U.S. population receives health care benefits through an employer.[192] However, based on enforcement experience under the 2016 and 2020 Rules, we believe that the proposed approach will minimize confusion among individuals seeking relief and will decrease the likelihood that individuals seeking relief under Federal Equal Employment Opportunity laws will miss strict time limits for filing complaints to challenge discrimination under those laws. The Department is proposing this language to promote clarity regarding the filing and processing of discrimination complaints. The Department proposes that employment discrimination complaints alleging violations of similar protections against discrimination to those that are covered under Section 1557 be handled by other Federal agencies under the statutes they enforce, and not by the Department. The Department would maintain jurisdiction over complaints alleging discrimination in covered health insurance or other health-related coverage; however, should the Department receive a complaint under Section 1557 alleging discrimination by an employer (such as a claim involving a Federal Employees Health Benefits plan), such a complaint will be referred to the appropriate Federal agency if it is determined that another agency (*e.g.,* Office of Personnel Management (OPM), Equal Employment Opportunity Commission (EEOC), or DOJ) may have jurisdiction under the statutes it enforces.

Proposed paragraph (c) provides that if any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

We seek comment on the effects of the proposed scope of application of the regulation, including the application to

[188] *Id.* 18116(a) (emphasis added).

[189] *Id.*

[190] Section 1311 of the ACA (codified at 42 U.S.C. 18031) (establishing grants and requiring those grants to be used by states to create ''American Health Benefit Exchanges'').

[191] 85 FR 37160, 37169 (June 19, 2020).

[192] Katherine Keisler-Starkey & Lisa N. Bunch, U.S. Dep't of Commerce, U.S. Census Bureau, Health Insurance Coverage in the United States: 2019, p. 4 (2020), *https://www.census.gov/content/dam/Census/library/publications/2020/demo/p60-271.pdf.*

programs and activities of the Department and other Executive Agencies; application of this part to recipients of Federal financial assistance from Executive Agencies other than the Department; and the application to employment.

Treatment of Title IX Exceptions

Section 1557 provides that ''an individual shall not, on the ground prohibited under'' Title VI, Title IX, the Age Act, and Section 504, ''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.'' [193] The statute further provides that ''[t]he enforcement mechanisms provided for and available under'' Title VI, Title IX, the Age Act, and Section 504 ''shall apply for purposes of violations of this subsection.'' [194] Section 1557 thus explicitly incorporates from those four statutes the grounds of discrimination that are prohibited and the enforcement mechanisms of the referenced statutes (Title VI, Title IX, the Age Act, and Section 504). Under the most natural understanding of Section 1557's text, as well as the statute's structure and purpose, the statutory term ''ground prohibited'' is best understood as incorporating the bases of the discrimination prohibitions in the referenced statutes (race, color, national origin, sex, age, and disability).

As discussed further below, the Department also believes that in order to construe particular terms in (or incorporated by) Section 1557, such as the meaning of ''sex'' or ''disability''; what it means to be ''subjected to discrimination'' on one of the specified grounds; the scope of ''program or activity''; and what counts as ''Federal financial assistance,'' it is reasonable and appropriate to look to how Congress, the agencies, and the courts have construed those terms under Title VI, Title IX, the Age Act, and Section 504. There is no similar basis, however, for concluding that Congress incorporated into Section 1557 any of the exceptions that Congress added to Title IX—the only one of the four statutes referenced by Section 1557 that contains such exceptions, and also the only statute with jurisdiction that is limited to a certain type of program or activity (*i.e.,* education programs or activities). At the very least, Section 1557 does not unambiguously require HHS to incorporate any of the Title IX exceptions into its regulatory scheme.[195]

Section 1681(a) of Title IX states the statute's basic prohibition on discrimination on the basis of sex, and then enumerates several circumstances in which that prohibition does not apply, which it denominates as ''exceptions'' from the basic rule of section 1681(a). The prohibition on sex-based discrimination does ''not apply'' at all, for example, ''to an educational institution whose primary purpose is the training of individuals for the military services of the United States, or the merchant marine'';[196] nor does it apply to any program or activity of the American Legion undertaken in connection with the organization or operation of any Boys State conference, Boys Nation conference, Girls State conference, or Girls Nation conference.[197] Title IX includes an exception for *admissions* decisions of educational institutions other than institutions of vocational education, professional education, graduate higher education, and public undergraduate institutions,[198] and yet another exception for the *membership* practices of certain tax-exempt social fraternities and sororities, the YMCA and YWCA, the Girl Scouts, the Boy Scouts, and voluntary youth service organizations whose membership has ''traditionally been limited to persons of one sex and principally to persons of less than nineteen years of age.'' [199] Title IX also contains exceptions that permit educational institutions to authorize father-son or mother-daughter activities,[200] and to award scholarships based upon the results of sex-specific beauty pageants.[201] Section 1681(a)(3) contains another exception for an educational institution controlled by a religious organization, which is permitted to engage in otherwise prohibited sex discrimination in particular circumstances—namely, where ''the application of [Title IX's nondiscrimination mandate] would not be consistent with the religious tenets of such organization.'' [202]

The 2016 Rule did not incorporate these Title IX exceptions for purposes of construing Section 1557. The treatment under the 2020 Rule is not as clear. Section 92.6(b) of the 2020 Rule states that ''[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, *exemptions,* affirmative rights, or protections provided by'' the four referenced nondiscrimination statutes (and several others that are listed), ''such application shall not be imposed or required.'' (Emphasis added.) The preamble to the 2020 Rule asserted that because Section 1557 ''incorporates the statutory *scope* of Title IX, . . . it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions . . . '' [203] Indeed, the preamble went so far as to say that ''this final rule amends the Department's Title IX regulation to explicitly incorporate relevant statutory exemptions from Title IX, including . . . the religious exemption.'' [204] The regulatory text of the 2020 Rule itself, however, does not expressly call for incorporation of the religious exemption nor repeat the specific language of that Title IX provision.[205]

[193] 42 U.S.C. 18116(a).

[194] *Id.*

[195] To the degree that there is any statutory ambiguity, the Department has discretion as to whether and how to incorporate other aspects of the referenced statutes. *See Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984) (courts should give ''considerable weight to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations, 'has been consistently followed whenever a decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations'").

[196] 20 U.S.C. 1681(a)(4).

[197] *Id.* 1681(a)(7).

[198] *Id.* 1681(a)(1).

[199] *Id.* 1681(a).

[200] *Id.* 1681(a)(8).

[201] *Id.* 1681(a)(9).

[202] The section 1681(a)(3) exception applies only to certain religiously affiliated *educational* institutions. The Civil Rights Restoration Act of 1987, however, contains a proviso that exempts application of Title IX to ''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,'' creating a parallel exception to that contained in section 1681(a)(3).

[203] 85 FR 37160, 37207–08 (June 19, 2020) (emphasis added).

[204] 85 FR 37162.

[205] Following issuance of the 2020 Rule, a consortium of plaintiffs filed a lawsuit against the Department in Federal district court, seeking to enjoin the Department from incorporating the Title IX religious exemption. Compl., *Whitman-Walker Clinic* v. *U.S. Dep't of Health & Human Servs.,* No. 1:20-cv-01630 (D.D.C. June 22, 2020) [hereinafter *Whitman-Walker* Complaint]; *see also* Compl. *BAGLY* v. *U.S. Dep't of Health & Human Servs.,* No. 20–11297, (D. Mass. July 9, 2020); Compl. *N.Y.* v. *U.S. Dep't of Health & Human Servs.,* No. 1:20-cv-05583 (S.D.N.Y. July 20, 2020). A little more than two weeks after the 2020 Rule went into effect, the court in *Whitman-Walker Clinic, Inc., et al.* v. *U.S. Dep't of Health & Human Servs.* preliminarily enjoined the Department ''from enforcing its incorporation of the religious exemption contained in Title IX.'' *Whitman-Walker Clinic* v. *U.S. Dep't of Health & Human Servs.,* 485 F. Supp. 3d 1, 37 (D.D.C. 2020). The court held that the Department's apparent inclusion of Title IX's religious exemption in the 2020 Rule violated the APA because the Department failed to consider ''the potential

Continued

This NPRM proposes not to import any of the Title IX exceptions into the Section 1557 regulation because the statutory language of Section 1557 is best interpreted to not authorize, and at the very least not command, the Secretary to promulgate such an extension of the Title IX exceptions.

The Department's analysis begins with the relevant statutory text. Section 1557 prohibits discrimination ''on the ground[s] prohibited under'' Title IX and the other referenced statutes.[206] The district court in *Franciscan Alliance* read the term ''ground'' to necessarily incorporate not only the prohibited basis for discrimination—*i.e.,* sex—but also any exceptions set forth in Title IX.[207] The Department believes that, as a textual matter, the more natural understanding of ''ground prohibited'' is that it refers simply to the basis on which discrimination is prohibited. Further, subsection (b) of Section 1557 refers to ''discrimination on any *basis* described in subsection (a),'' which suggests that ''ground'' in subsection (a) means the ''basis'' for discrimination, *i.e.,* race, color, national origin, sex, age, and disability.[208]

Recent Supreme Court opinions support the Department's reading. In an April 2022 decision, the Court used the term ''grounds'' when discussing prohibited bases for discrimination in several antidiscrimination statutes, including Section 1557.[209] Additionally, in the *Bostock* decision, the Court also used the term ''grounds'' in interpreting Title VII, while also referring separately to Title VII's ''express statutory exception for religious organizations.'' [210]

As a matter of ordinary speech, it would be uncommon to refer to a provision ''excepting'' particular entities from a statutory prohibition on discrimination as part of the ''ground prohibited'' by the statute from which they are excepted. The preamble to the 2020 Rule assumed that Section 1557 ''incorporates the statutory *scope* of Title IX''—which it understood to include Title IX's exceptions.[211] But nowhere does Section 1557 state that it incorporates the full ''scope'' of those statutes. The better reading of the text of Section 1557, then, is that it expressly incorporates the ''grounds'' and ''enforcement mechanisms'' of the four antidiscrimination statutes, but not their scope. Instead, the text of Section 1557 provides its own scope of application—to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under'' Title I of the ACA.[212] Therefore, the best reading of Section 1557 is that it does not incorporate Title IX's religious exception or any of the other Title IX exceptions.

Section 1557's structure confirms that textual understanding. The statute explicitly incorporates ''[t]he enforcement mechanisms provided for and available under'' the referenced statutes.[213] That provision demonstrates that when Congress wanted to incorporate aspects of the referenced statutes other than the ''grounds'' of prohibited discrimination, it did so expressly. There is, by contrast, no such express incorporation of the Title IX exceptions. To the contrary, the very first words of Section 1557 are that ''*[e]xcept as otherwise provided for in this title (or an amendment made by this title),* an individual shall not, on the ground prohibited under [the four referenced statutes], 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 . . .'' [214] Congress, in other words, specifically signaled that the only ''except[ions]'' to Section 1557's prohibition would be those ''provided for'' or ''made by'' Title I of the ACA, which does *not* encompass Title IX of the Education Amendments of 1972.

Furthermore, Section 1557's role as a health care statute further supports the Department's reading of the text and understanding of Congress' intent. The Title IX exceptions are specifically concerned with educational institutions and other recipients of Federal funds that operate an education program or activity. The apparent reasons for the exceptions in the education setting would, at least in many cases, be inappropriate or nonsensical in the context of health programs and activities. For example, Title IX exceptions related to the membership practices of social fraternities, sororities, YWCA, YMCA, Girls Scouts, Boys Scouts, and voluntary youth service organizations; father-son and mother-daughter activities; and beauty pageant-based scholarships are ill-suited for application to health programs and activities.

Moreover, the application of the Title IX exception for entities controlled by religious organizations, in particular, could raise distinctive concerns in the health care context that are not typically present in education programs and activities. Health care settings differ significantly from educational settings with respect to both the ability of affected parties to choose or avoid a certain religiously affiliated health care institution and the urgency of the need for services provided by the covered entities.[215] For example, access to health care settings raises considerations of choice and notice to affected parties that are largely absent in the educational context. Whereas students and families typically make a choice to attend religious educational institutions, patients seeking health care are much more likely to be driven by considerations of availability, convenience, urgency, geography, cost, insurance network restrictions, and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization. There are an increasing number of communities in the United States with limited options to access health care from non-religiously affiliated health care providers.[216] As a practical matter, then, many patients and their families may have little or no choice about where to seek care, particularly in exigent circumstances, or in cases where the quality or range of care may vary dramatically among providers. Moreover, health care consumers are not always aware that the health care entities from which they seek care may

negative consequences that importing a blanket religious exemption into Section 1557 might have for access to health care.'' *Id.* (citing *Mfrs. Ass'n* v. *State Farm Mut. Auto Ins.,* 463 U.S. 29, 42 (1983) (agency must examine relevant date and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made)). The preliminary injunction issued by the court in *Whitman-Walker* remains in effect.

[206] 42 U.S.C. 18116(a).

[207] *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 690–91 (N.D. Tex. 2016).

[208] 42 U.S.C. 18116(b) (emphasis added).

[209] *Cummings* v. *Premier Rehab Keller, P.L.L.C.,* 142 S. Ct. 1562, 1569 (2022) (''Congress has enacted four statutes prohibiting recipients of Federal financial assistance from discriminating based on certain protected grounds.'').

[210] *Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731, 1742, 1754 (2020).

[211] 85 FR at 37208.

[212] 42 U.S.C. 18116(a).

[213] *Id.* § 18116.

[214] *Id.* 18116(a) (emphasis added).

[215] 81 FR 31375, 31380 (May 18, 2016).

[216] *See, e.g.,* Maryam Guiahi et al., *Patient Views on Religious Institutional Health Care,* 2 JAMA Network Open, Dec. 27, 2019, at p. 2, *https://pubmed.ncbi.nlm.nih.gov/31880794/* (discussing growing religious ownership of health care entities in the context of whether U.S. adults consider religious affiliation when selecting health care facilities); Michael Booth, *SCL Health to Merge with Intermountain Health, Creating Not-For-Profit Hospital Giant in West,* The Colorado Sun (Sept. 16, 2021), *https://coloradosun.com/2021/09/16/hospital-merger-scl-health-colorado/.*

be limited in the care they provide.[217] Incorporation of Title IX's religious exception would therefore seriously compromise Congress's principal objective in the ACA of increasing access to health care.

While not incorporating the Title IX religious exception, the Department is fully committed to respecting conscience and religious freedom laws when applying this rule, including an organization's assertion that the provisions of this rule conflict with their rights under Federal conscience and religious freedom laws as addressed in proposed § 92.302.

The application of these statutes, all of which Congress enacted *after* it enacted Title IX, protects important religious liberty interests and conflicts of conscience, even without the incorporation of the Title IX religious exception into Section 1557. Under RFRA, exemptions from any of the antidiscrimination requirements of Section 1557 would depend in part on the ramifications of applying such exemptions. For example, even if the rule substantially burdened religious practices, a religious exemption would not be required if that burden was the result of the government's advancement of a compelling interest by means that were least restrictive of religious exercise in particular contexts. The U.S. Supreme Court has made it clear that a fact-sensitive, case-by-case analysis of such burdens and interests is needed under RFRA, something the Title IX exception does not allow.[218] The Department will apply RFRA in this manner.

Applying the existing Federal conscience and religious freedom laws will allow the Department to address the interests in providing nondiscriminatory health care and religious or conscience commitments by applying the legal standards applicable to those conscience and religious freedom laws. It was reasonable for Congress to rely upon existing conscience and religious freedom laws to protect religious exercise and respect conscience in appropriate cases, rather than to import the Title IX religious exception[219] into Section 1557.

We seek comment on the approach proposed in this NPRM and particularly invite comments from covered entities controlled by or affiliated with religious organizations; providers employed by such entities; and people who receive health care from religiously affiliated medical providers and entities.

Relationship to Other Laws (§ 92.3)

Proposed § 92.3 explains the relationship of the proposed regulation to existing laws. Paragraph (a) provides that Section 1557 is not intended to apply lesser standards for the protection of individuals from discrimination than the standards under Title VI, Title IX, Section 504, the Age Act, or the regulations issued pursuant to those laws.

Consistent with the statute, paragraph (b)(1) states that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under the Federal civil rights laws cited in 42 U.S.C. 18116(b) (Title VI, Title VII, Title IX, Section 504, and the Age Act).

We note here that Title II of the Americans with Disabilities Act[220] (ADA) prohibits discrimination on the basis of disability by public entities (*i.e.,* State and local governments and their agencies) and is modeled on Section 504.[221] Title II of the ADA and Section 504 are generally understood to impose substantially the same requirements, given that Congress enacted the ADA to extend Section 504's existing protections beyond Executive Agencies and recipients of Federal funds,[222] and the Congressional directive that the ADA be construed to grant at least as much protection as provided by Section 504 and the regulation implementing Section 504.[223] Following the passage of the ADA, the Rehabilitation Act Amendments of 1992 revised the Rehabilitation Act's findings, purpose, and policy provisions to incorporate language acknowledging the discriminatory barriers faced by individuals with disabilities, and to recognize that individuals with disabilities have the right to ''enjoy full inclusion and integration in the economic, political, social, cultural and educational mainstream of American society.'' [224] The Senate Report concerning the Rehabilitation Act Amendments of 1992 states that the purpose and policy statement is ''a reaffirmation of the precepts of the Americans with Disabilities Act'' and that these principles are intended to guide the Rehabilitation Act's policies, practices, and procedures.[225]

Accordingly, a number of the changes that the Department is proposing for specific disability-related provisions in the Section 1557 regulation, which encompasses Section 504's ground for discrimination, conform to DOJ's implementing regulation for Title II of the ADA, many of which were updated in 2010. Where the Department has made changes to its Section 1557 regulation to correspond to provisions in DOJ's Title II regulation, the Department encourages individuals to look to the corresponding Title II guidance and section-by-section analysis for guidance on how to interpret these provisions.[226]

The Department also notes that there may be overlap among different Federal civil rights statutes, and that certain Section 504 requirements and terminology may be specific to the programs and activities that are funded or conducted by the relevant Federal agency. For example, if a covered entity is a recipient of Federal financial assistance from the Department of Housing and Urban Development (HUD), HUD's Section 504 regulation, which contains distinct requirements and terminology related to housing, would also apply.

Proposed paragraph (b)(2) provides that nothing in Section 1557 shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals

[217] *See, e.g.,* Coleman Drake et al., *Market Share of US Catholic Hospitals and Associated Geographic Network Access to Reproductive Health Services,* Jama Network Open, Jan. 29, 2020, *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2759762* (research study examining the impact and growth of Catholic health care entities on the provision of reproductive health care in the United States); Harris Meyer, *Most Catholic Hospitals Don't Disclose Religious Care Restrictions,* Modern Healthcare, Mar. 15, 2019, *https://www.modernhealthcare.com/operations/most-catholic-hospitals-dont-disclose-religious-care-restrictions.*

[218] *See, e.g., Gonzales* v. *O Centro Espírita Beneficente União do Vegetal,* 546 U.S. 418, 430–31 (2006) (when applying RFRA, courts look ''beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants''); *cf. Ramirez* v. *Collier,* 142 S. Ct. 1264, 1281 (2022) (holding that the Religious Land Use and Institutionalized Persons Act, which applies RFRA's test for religious exemptions in the prison context, ''requires that courts take cases one at a time, considering only 'the particular claimant whose sincere exercise of religion is being substantially burdened'''') (quoting *Holt* v. *Hobbs,* 574 U.S. 352, 363 (2015)).

[219] A religiously controlled covered entity that operates an education program or activity that is entitled to a religious exemption under Title IX would follow the Department's Title IX regulation at 45 CFR 86.12.

[220] Public Law 101–336, 104 Stat. 327 (1990) (codified as amended at 42 U.S.C. 12101, *et seq.*).

[221] 42 U.S.C. 12132 (''[N]o qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.'').

[222] *See Berardelli* v. *Allied Servs. Inst. of Rehab. Med.,* 900 F.3d 104, 115 (3d Cir. 2018).

[223] *See, e.g.,* 42 U.S.C. 12201(a).

[224] 29 U.S.C. 701(a)(3), as amended.

[225] S. Rep. 102–357, at 14 (Aug. 3, 1992); H.R. Rep. 102–822, at 81 (Aug. 10, 1992).

[226] *See* 28 CFR pt. 35, app. A, B, C.

asserting rights under Federal conscience or religious freedom laws. These would include statutory protections under RFRA and the Coats-Snowe Amendment,[227] the Church Amendments,[228] section 1303 of the ACA,[229] section 1553 of the ACA,[230] and the Weldon Amendment.[231]

Under the 2016 Rule, former § 92.2(b)(2) provided that if an application of Section 1557 requirements violated applicable Federal statutory protections for conscience and religious exercise, application of Section 1557 was not required.[232] The 2020 Rule, at § 92.6(b), provides that Section 1557 will not apply if such application would ''violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections'' of the Coats-Snowe Amendment, Church Amendments, RFRA, Section 1553 of the ACA, Section 1303 of the ACA, Weldon Amendment, or ''any related, successor, or similar Federal laws or regulations.'' [233] The Department has considered the current regulatory language and has determined that the 2020 Rule also fails to provide sufficient information to covered entities and beneficiaries regarding how OCR will approach any apparent interaction between Section 1557 requirements and the enumerated protections. Further, the 2020 Rule preamble and Regulatory Impact Analysis (RIA) failed to consider potential harms to third parties that may result from granting a religious exemption in the health care context—a consideration that can be relevant to the RFRA analysis in a particular case.[234] The Department acknowledges and respects laws protecting conscience and religious exercise. The Department believes the approach in this proposed rule will ensure that all constitutional and statutory rights are protected and seeks comment on this approach. We further address exemptions under Federal conscience and religious freedom laws at proposed § 92.302.

Definitions (§ 92.4)

Proposed § 92.4 contains proposed definitions, which is the same approach taken in the 2016 Rule at former § 92.4. The 2020 Rule does not include a specific definition section, an approach that contributes to uncertainty. We reintroduce definitions to help reinstate clarity. For ease of organization, definitions are discussed below by topic area, and definitions of particular note are set out in additional detail.

We propose to define a range of terms related to disability discrimination, including: auxiliary aids and services; disability; qualified individual with a disability; qualified interpreter for an individual with a disability; and qualified reader. These definitions appeared in the 2016 Rule and have not been changed substantively, with the exception of the addition of the term ''qualified reader,'' which incorporates the definition of ''qualified reader'' from the ADA Title II regulation [235] to provide clarity to both covered entities and protected individuals about the necessary qualifications of a reader when required under this regulation. Any other differences between the definitions proposed herein and the 2016 Rule were made to update appropriate citations.

We also propose to define a range of terms related to language access, including limited English proficient individual; language assistance services; qualified bilingual/multilingual staff; qualified interpreter for a limited English proficient individual; and qualified translator. These definitions appeared in the 2016 Rule and have not been changed substantively. Terminology has been revised to read ''limited English proficient individual,'' rather than ''individual with limited English proficiency,'' as ''limited English proficient individual'' reflects widely used terminology. The Department also proposes to provide more detail in the definition of ''limited English proficient individual'' to explain that a limited English proficient individual may be competent in English for certain types of communication (*e.g.,* speaking or understanding), but still be LEP for other purposes (*e.g.,* reading or writing). This language will assist covered entities in understanding that a person who has proficiency in English in one context (*e.g.,* speaking) may still require assistance in another context (*e.g.,* receiving translated documents). The Department welcomes comment on this change in terminology.

We also propose to define terms related to covered entities and other entities addressed in the rule, including applicant; companion; covered entity; Department; Director; Exchange; Federally-facilitated Exchange; OCR; recipient; State Exchange; and Title I Entity. These definitions were included in the 2016 Rule and have not been changed substantively, though we have replaced the term ''Marketplace'' with ''Exchange'' to reflect the terminology used in Departmental regulations defining the term.[236] The terms ''age'' and ''national origin'' are also defined, with the same definitions as provided in the 2016 Rule.

Particular definitions of note are included below.

Federal financial assistance. We propose to include the definition of Federal financial assistance found in former § 92.4 of the 2016 Rule, with slight modifications. The 2020 Rule does not include a definition of this term.

We propose the definition of ''Federal financial assistance'' to include grants, loans, and other types of assistance from the Federal Government, in accordance with the definition of the term in the Section 504 and the Age Act implementing regulations at 45 CFR 84.3(h) and 91.4, respectively. We also propose to specifically include credits, subsidies, and contracts of insurance, in accordance with the statutory language of Section 1557. Examples of HHS programs that provide Federal financial assistance subject to this part include but are not limited to Medicaid and CHIP, Medicare Part A, Medicare Part B (as proposed in this rule), Medicare Part C (Medicare Advantage), Medicare Part D (drug coverage), and HHS grant programs.

As discussed previously, similar to the 2016 and 2020 Rules, this proposed rule applies only to Federal financial assistance from HHS and does not apply to health programs or activities receiving Federal financial assistance from other Federal agencies.[237] While the Section 1557 statute applies to all Executive Agencies, the Department continues to believe that it is appropriate to limit this proposed rule to health programs or activities that receive Federal funding from the Department, which is within the Department's area of expertise. We encourage other Federal agencies to use this proposed rule as a template for developing their own Section 1557 regulations and policies applicable to their federally assisted health programs or activities.

We propose to include a clause to clarify the Federal financial assistance

[227] 42 U.S.C. 238n.

[228] *Id.* 300a–7.

[229] *Id.* 18023(b)(2)(A).

[230] *Id.* 18113.

[231] Consolidated Appropriations Act, 2022, Public Law 117–103, div. H, title V General Provisions, § 507(d)(1) (Mar. 15, 2022).

[232] 81 FR 31375, 31381 (May 18, 2016).

[233] 45 CFR 92.6(b).

[234] *See, e.g., Whitman-Walker Clinic* v. *U.S. Dep't of Health & Human Servs.,* 845 F. Supp. 3d 1, 45–46 (D.D.C. 2020).

[235] 28 CFR 35.104.

[236] 45 CFR 155.20 (defining ''Exchange'' and ''Federally-facilitated Exchange''); § 155.100 (providing for establishment of an Exchange by a State).

[237] 81 FR 31375, 31379 (May 18, 2016); 85 FR 37160, 37170 (June 19, 2020).

includes Federal financial assistance that the Department plays a role in providing or administering. This includes advance payments of the premium tax credit and cost-sharing reduction payments under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department. This is similar to, but differs slightly from, the 2016 Rule by clarifying that the Federal financial assistance that the Department plays a role in providing or administering includes the ''advance payments of the premium tax credit and cost-sharing reduction payments,'' which are the relevant credit and subsidy payments under Title I of the ACA that the Department plays a role in providing or administering. The language in this provision was informed by the definition of ''Federal financial assistance'' in the regulation implementing Title IX at 45 CFR 86.2(g). That Title IX regulatory provision clarifies that Federal financial assistance includes wages, loans, grants, scholarships, and other monies that are given to any entity for payment to or on behalf of students who are admitted to that entity or that are given directly to these students for payment to that entity.[238]

In the health care context, Federal funds are provided on behalf of eligible individuals for advance payments of the premium tax credit and cost-sharing reductions (also referred to as cost-sharing subsidies) to ensure the affordability of health insurance coverage purchased through the Health Insurance Exchanges. As in the 2016 Rule, we have added language to this proposed definition stating that such funds, as well as payments, subsidies, or other funds extended by the Department, are Federal financial assistance covered by the Rule when extended to the entity providing the health insurance coverage or services, whether they are paid directly by the Federal Government to that entity or to the individual for payment to the entity providing health insurance coverage or services. Thus, an issuer participating in any Health Insurance Exchange is receiving Federal financial assistance when advance payments of the premium tax credit or cost-sharing subsidies are provided on behalf of any of the issuer's enrollees. A health services provider that contracts with such an issuer does not become a recipient of Federal financial assistance by virtue of the contract but would be a recipient if the provider otherwise receives Federal financial assistance, such as through participation in Medicare or Medicaid.

The 2020 Rule did not include language regarding Federal financial assistance that the Department plays a role in providing or administering. The Department asserted in the preamble of the 2020 Rule that the 2016 definition was overbroad. This interpretation fails to consider the statutory language of Section 1557, which specifically includes ''credits'' and ''subsidies'' as Federal financial assistance, in conjunction with the entirety of Title I of the ACA, which specifically grants the Secretary clear authority over the programs for which the Department plays a role in providing or administering Federal financial assistance. These Title I programs include the advance payments of the premium tax credit and cost-sharing reductions,[239] as well as pass-through funding available to states through section 1332 waivers.[240]

The Department plays a role in providing or administering advance payments of the premium tax credit and cost-sharing reductions as set forth in Title I of the ACA, which specifies that the Secretary of HHS, ''in consultation with the Secretary of the Treasury, shall establish a program'' for advance payments of the premium tax credit and cost-sharing reductions.[241] HHS advises the Department of the Treasury of the amounts of advance payments of the premium tax credit and cost-sharing reductions and works with Department of the Treasury to make payments to issuers.[242]

The Department notes that it is not currently making cost-sharing reduction payments to issuers. On October 11, 2017, the Attorney General issued a legal opinion that HHS did not have a valid appropriation with which to make cost-sharing reduction payments to issuers.[243] As a result, the cost-sharing reduction payments ceased as of October 12, 2017.[244] If issuers receive cost-sharing reduction payments in the future from the Department, such payments would be considered Federal financial assistance under this proposed rule similar to the advance payments of the premium tax credit.

Similarly, the Department plays a role in providing or administering pass-through funding available to states through section 1332 waivers.[245] Section 1332 of the ACA provides that states may apply to the Department of Health and Human Services and the Department of the Treasury for waivers of certain ACA requirements in the individual and small group markets if the waiver satisfies certain statutory requirements.[246] Section 1332(a)(3) of the ACA directs the Department of Health and Human Services and the Department of the Treasury to pay pass-through funding to the state for the purpose of implementing the state section 1332 waiver plan and outlines accompanying requirements for making the pass-through funding determination.[247] The amount of Federal pass-through funding is equal to the amount, determined annually by the Department of Health and Human Services and the Department of the Treasury, of the premium tax credit under section 36B of the Internal Revenue Code, the small business tax credit under section 45R of the Internal Revenue Code, or cost-sharing reductions under ACA Title I, part I of subtitle E, that individuals and small employers in the state would otherwise be eligible for had the state not received approval for its section 1332 waiver. This calculation includes any amount not paid due to an individual or small employer not qualifying for the premium tax credit, small business tax credit, or cost-sharing reductions or qualifying for a reduced level of such financial assistance.[248]

As with the advance payments of the premium tax credit, HHS plays a role in providing the section 1332 pass-through funding by working with the Department of the Treasury in calculating the pass-through funding amount and administering the pass-

[238] 45 CFR 86.2(g)(1)(ii).

[239] Section 1412 of the ACA, codified at 42 U.S.C. 18082.

[240] Section 1332(a)(3) of the ACA, codified at 42 U.S.C. 18052(a)(3).

[241] Section 1412 (a)–(c) of the ACA, codified at 42 U.S.C. 18082(a)–(c).

[242] *Id.*

[243] Memorandum from Eric Hargan, Acting Sec'y, Dep't of Health & Human Servs., to Seema Verma, Admin'r, Ctrs. for Medicare & Medicaid Servs. (enclosing Attorney General Jeff Sessions' legal opinion, dated October 11, 2017, regarding cost-sharing reduction payments) (Oct. 12, 2017), *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

[244] *Id.*

[245] Section 1332(a)(3) of the ACA, codified at 42 U.S.C. 18052(a)(3).

[246] Section 1332(a) of the ACA, codified at 42 U.S.C. 18052(a). States with approved waivers have specific terms and conditions (STCs) that the state must also comply with all applicable Federal statutes relating to nondiscrimination, including Section 1557. *See e.g.,* Ctrs. for Medicare & Medicaid Servs., approval of Colorado's extension application for a section 1332 State Innovation Waiver, STC 4 (Aug. 13, 2021), *https://www.cms.gov/files/document/1332-co-extension-approval-letter-stcs.pdf.*

[247] *See* Section 1332(a)(3) of the ACA, codified at 42 U.S.C. 18052(a)(3), and implementing regulations at 31 CFR 33.122, 45 CFR 155.1322.

[248] 31 CFR 33.122; 45 CFR 155.1322; 86 FR 53412 (Sept. 27, 2021).

through funds to the state.[249] We also note that any entity receiving section 1332 pass-through funds from the state would also be a recipient of Federal financial assistance from HHS under Section 1557.

In conclusion, in all of these programs, the ACA establishes that the Secretary of HHS is involved in calculating the amounts of Federal financial assistance and sets forth the Secretary's role in administering the programs. For these reasons, we are reinstituting the provision that Federal financial assistance for purposes of HHS' jurisdiction under this part includes that Federal financial assistance which the Department plays a role in providing or administering.

Health program or activity. The Department proposes to adopt a definition of ''health program or activity.'' The 2016 Rule contained such a definition. Among other things, the 2016 Rule defined ''health program or activity'' to include all of the operations of entities principally engaged in health services, health insurance coverage, or other health-related coverage, including ''a hospital, health clinic, group health plan, health insurance issuer, physician's practice, community-based health care providers, nursing facility, residential or community-based treatment facility, or other similar entity.'' [250] In contrast, the 2020 Rule does not provide a definition but rather addresses the term ''health program or activity'' in the application section of the rule at § 92.3(b). While defining ''health program or activity'' to encompass ''all of the operations of entities principally engaged in the business of providing health care,'' the 2020 Rule explicitly provides that ''an entity principally or otherwise engaged in the business of providing health insurance shall *not,* by virtue of such provision, be considered to be principally engaged in the business of providing health care.'' [251]

The Department believes that returning to a definition of ''health program or activity'' provides covered entities with important information regarding the types of operations that will be covered for purposes of this proposed rule. Whereas Title VI, Section 504, and the Age Act apply to *all* federally funded programs or activities, Section 1557 applies only to *health* programs or activities, just as Title IX applies only to *education* programs or activities. In determining the application of Section 1557, therefore, the Department has looked to the analogous ways in which ''education program or activity'' is understood under Title IX.

In paragraph (a), we propose to define health program or activity to mean any project, enterprise, venture or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage; provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage; provide clinical, pharmaceutical, or medical care; engage in health research; or provide health education for health care professionals or others. Coverage of health research and health education was discussed in the preamble to the 2016 Rule [252] but neither was mentioned in the 2020 Rule or preamble.

It has long been understood under the ''fungibility of funds'' rationale that Title IX applies to all the operations of entities principally engaged in educational functions, primarily on the theory that funds provided to such an entity invariably subsidize education operations. So, for instance, Title IX applies to not only the ''traditional educational operations'' of such an institution but also to ''faculty and student housing, campus shuttle bus service, campus restaurants, the bookstore, and other commercial activities.'' [253] Likewise, it is fair to assume Congress intended the nondiscrimination requirements of Section 1557 to apply categorically to entities principally engaged in the provision or administration of health-related activities, based upon the same ''fungibility of funds'' rationale. Indeed, Section 1557 specifically applies to ''any health program or activity, *any part of which* is receiving Federal financial assistance,'' [254] which appears to contemplate the application of such a ''fungibility of funds'' understanding.

The Department, at paragraph (b), thus proposes to define ''health program or activity'' to include all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings described in paragraph (a). Such entities include but are not limited to a: state or local health agency; hospital; health clinic; health insurance issuer; physician's practice; pharmacy; community-based health care provider; nursing facility; residential or community-based treatment facility; or other similar entity or combination thereof. We are proposing that whether such entities are administered by a government or a private entity, all of their operations would be covered under this part.[255] The 2016 Rule contained a similar provision, which also specifically referred to ''all of the operations of a State Medicaid program, a Children's Health Insurance Program, and the Basic Health Program.'' [256] We do not propose to expressly list Medicaid programs, CHIP, or the Basic Health Program in paragraph (b) because we believe they would be covered in their entirety as operations of state or local health agencies. We seek comment as to whether such programs should be explicitly referenced in the regulatory language.

Unlike under the 2020 Rule, we propose to apply this rule to all the operations of a recipient entity principally engaged in the provision or administration of health insurance coverage or other health-related coverage. We believe that the most natural reading of the language ''health program or activity'' in the statute encompasses health insurance programs or activities. In the preamble to the 2020 Rule, the Department emphasized that the provision of health-care *insurance* is not necessarily a form of health*care.* Whether or not that is true in any practical sense for purposes that bear on the application of nondiscrimination protections, the applicability of Section 1557 does not turn on whether a program or activity involves health care as such—it depends instead on whether the operations in question are a ''*health* program or activity''—something that unequivocally describes the operations of health insurance issuers.[257]

This straightforward textual reading is reinforced by the ACA's structure and clear indicia of the statute's purpose. Section 1557 forms a key part of the ACA—a law that itself focuses on health insurance market reforms as a means of expanding access to and provision of health care. Given the ACA's focus on

[249] 42 U.S.C. 18052(a)(3).

[250] Former 45 CFR 92.4.

[251] 45 CFR 92.3(b), (c) (emphasis added).

[252] 81 FR 31385.

[253] S. Rep. No. 64 at 17, reprinted in 1988 U.S.C.C.A.N. at 19; *see also* U.S. Dep't of Justice, Title IX Legal Manual, sec. C.3., n. 28 (citing H.R. Rep. No. 98–829, at 27 (1984), and noting that though this comment was made in reference to an earlier draft of the CRRA, ''sponsors of the CRRA, as eventually enacted, later noted that, despite the new language, coverage would operate in the same manner envisioned for the prior bill'').

[254] 42 U.S.C. 18116(a) (emphasis added).

[255] *See, e.g., Fain* v. *Crouch,* 545 F. Supp. 3d 338, 343 (S.D.W. Va. 2021) (holding that defendant health plan was, ''by virtue of its acceptance of Federal assistance under its Medicare Advantage program,'' required to comply with Section 1557 ''under its entire portfolio'').

[256] Former 45 CFR 92.4 (defining ''health program or activity'').

[257] *See, e.g., Fain,* 545 F. Supp. 3d at 342 (''health program or activity' under Section 1557 necessarily includes health insurance issuers'').

health insurance and other health-related coverage, if Congress intended to exclude health insurance from Section 1557's reach, it is logical to assume that it would have done so expressly.

In enacting the ACA, Congress showed a clear intent to protect individuals from discrimination in health insurance and other health-related coverage and to regulate the content of such coverage. As further evidence that Congress intended the ACA to prohibit discriminatory practices in health insurance and other health-related coverage, in addition to the protections against discrimination afforded under Section 1557, Congress enacted the ACA's market reforms that prohibited certain common discriminatory practices in health insurance benefit designs.[258]

By including a nondiscrimination provision in Title I of the ACA, a title of the health care law that predominantly addresses access to and the design of health insurance and other health-related coverage, Congress demonstrated an intent to apply the non-discrimination provision to health insurance issuers that receive financial support from the Federal Government. Private health insurance issuers play a critical role in ensuring that people are able to receive care within the current health care system. Issuers exercise significant control over enrollees' ability to access their health care by strongly influencing which providers they see, which hospitals they visit, and which treatments or medications they receive.[259] Indeed, a recent district court opinion on this issue found that, by virtue of being the ''gatekeeper'' of the plaintiff's health care, a health plan qualified as a '' 'health program' that Congress intended to rid of discrimination.'' [260] This proposed rule is consistent with that reading.

We note that the 2016 Rule included group health plans [261] as among the entities that were categorically covered for all of their operations. We propose to not explicitly include group health plans in the non-exhaustive list of entities identified in proposed paragraph (b). Although we still consider group health plans to be principally engaged in providing or administering health programs or activities described in paragraph (a), many group health plans themselves are not recipients of Federal financial assistance (as opposed to the employer or plan sponsor offering the group health plan or the third party administrator administering the group health plan), so inclusion of group health plans on the list may be confusing. That said, if the Department receives a complaint against a group health plan, we will evaluate the facts on a case-by-case basis to determine whether the group health plan is a covered entity subject to this part.

We note that even if the Department determines that a group health plan is not covered under this part, other entities that contract with a group health plan or a sponsor of a group health plan may be covered entities. For example, recipient health insurance issuers principally engaged in providing or administering health insurance coverage would be covered for health insurance they provide to a fully-insured group health plan and also for third party administrator activities that they are responsible [262] for providing in a self-funded group health plan.[263] The Department will evaluate the facts on a case-by-case basis to determine whether other entities that contract with a group health plan are covered entities subject to this part. Further, though a group health plan may not be covered under Section 1557, it may still be subject to other Federal nondiscrimination requirements. For example, group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage are prohibited from establishing any rule for eligibility, benefits, or premiums or contributions that discriminates based on any health factor.[264]

We seek comment on the circumstances under which a group health plan might receive funds that could be considered Federal financial assistance from the Department, including the type and prevalence of funds received that could be considered Federal financial assistance under this part.

Finally, we emphasize that proposed paragraph (b) is not intended to serve as an exhaustive list of those entities HHS believes would qualify as principally engaged in the provision or administration of health programs or activities described in paragraph (a). For example, we propose to expressly refer to hospitals but not to refer to other common names, such as medical centers, for the same or similar entities. Similarly, we propose not to expressly include hospital systems or healthcare systems, even though in many instances they will fall within the scope of

[258] 42 U.S.C. 18022(b)(4)(B)–(C) (in defining essential health benefits, the Secretary of HHS must ''take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups,'' and ''not make coverage decisions . . . or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life''); 18031(c)(1)(A) (criteria for qualified health plans require plans to ''not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs''); 300gg (prohibiting discriminatory premium rates by limiting rating factors to only include family size, geographic rating area, age, and tobacco use); 300gg–4 (prohibiting discrimination against individual participants and beneficiaries based on health status by prohibiting establishment of rules for eligibility (including continued eligibility) based on the following health-status-related factors: (1) Health status; (2) Medical condition (including both physical and mental illnesses); (3) Claims experience; (4) Receipt of health care; (5) Medical history; (6) Genetic information; (7) Evidence of insurability (including conditions arising out of acts of domestic violence); (8) Disability; (9) Any other health status-related factor determined appropriate by the Secretary).

[259] Additionally, many health insurance issuers are directly involved in the provision of care through administration of a health maintenance organization (HMO). An HMO is a health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO.

[260] *Fain,* 545 F. Supp. 3d at 342 (holding that defendant health plan was a ''health program or activity'' for purposes of Section 1557 jurisdiction).

[261] ''Group health plan'' is defined as ''an employee welfare benefit plan to the extent that the plan provides medical care (as defined in paragraph (2) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of Title 26).'' 29 U.S.C. 1191b(a)(1); *see also* 42 U.S.C. 300gg–91(a). ''Employee welfare benefit plan'' is defined as ''any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits, apprenticeship or other training programs, or day care centers, scholarship funds, or prepaid legal services, or (B) any benefit described in section 186(c) of this title (other than pensions on retirement or death, and insurance to provide such pensions).'' 29 U.S.C. 1002(1).

[262] *See, e.g., Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017) (holding that a third party administrator could be liable under Section 1557 for damages arising from discriminatory terms in a self-funded employer-provided health plan if the third party administrator provided the employer with a discriminatory plan document, notwithstanding the fact that the employer subsequently adopted the plan and maintained control over its terms).

[263] *See* discussion *infra* under proposed § 92.207 on application to third party administrators.

[264] 45 CFR 147.110 (HHS); 29 CFR 2590.715–2705 (Department of Labor); 26 CFR 54.9815–2705 (Department of the Treasury). We note that grandfathered and non-grandfathered group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan are prohibited from establishing any rule for eligibility, benefits, or premiums or contributions that discriminates based on any health factor pursuant to 45 CFR 146.121 (HHS); 29 CFR 2590.702 (Department of Labor); 26 CFR 54.9802–1 (Department of the Treasury).

paragraph (b). For example, under proposed (b), the rule could cover all of the operations of a non-profit healthcare system operating five hospitals, depending on the specific facts. HHS will evaluate the facts, on a case-by-case basis, to determine whether an entity falls within the scope of paragraph (b)'s categorical coverage. We invite comments on whether it is important to add any other entities to the list in (b) in order to further clarify coverage.

Machine translation. We propose to define ''machine translation'' as automated translations, without the assistance of or review by a qualified human translator, that are text-based and provide instant translations between various languages, sometimes with an option for audio input or output. This is in contrast to human translation, which is context-based and captures the intended meaning of the source. This definition is based on literature addressing the use of machine translation in the clinical setting, which we believe captures the automated translations that are being used in the health care setting.[265] We seek comment on the adequacy of this definition.

Assurances Required (§ 92.5)

This proposed rule would retain the requirement of the 2016 and 2020 Rules for recipients to submit assurances of compliance to the Department. One method that the Federal Government uses to ensure civil rights compliance is to require covered entities to submit assurances of compliance when applying for Federal financial assistance. The assurances and related certification documents remind covered entities of their civil rights obligations and can also assist the Department in pursuing an independent contract claim for enforcement of nondiscrimination requirements.[266]

Specifically, proposed § 92.5 is the same as § 92.4 of the 2020 Rule. In proposed paragraph (a), each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance Exchange, and each state seeking approval to operate a State Exchange is required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557, Title VI, Title IX, Section 504, and the Age Act. The duration of obligation (proposed paragraph (b)), and covenants language (proposed paragraph (c)) adopt the corresponding requirements found in the Section 504 regulation at 45 CFR 84.5.

Remedial Action and Voluntary Action (§ 92.6)

The Department proposes to include requirements regarding remedial and voluntary action, which would reinstate former § 92.6 in the 2016 Rule. The 2020 Rule repealed former § 92.6, stating that it was duplicative and overlapped with existing civil rights laws and regulations, and therefore would cause confusion about the responsibilities of covered entities.[267] The regulations implementing Title IX, Section 504, and the Age Act do require a covered entity to take voluntary action upon a determination that the entity engaged in discriminatory conduct.[268] The Department believes that, rather than causing confusion, proposed § 92.6 clarifies that Section 1557 also requires covered entities that have engaged in discriminatory conduct with respect to their health programs and activities in violation of this part to take voluntary actions to remediate the effects of such discriminatory conduct. Where a covered entity is required to take remedial actions under Title VI, Section 504, Title IX, or the Age Act, such actions would likely satisfy the remedial actions required by proposed § 92.6.

Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)

Proposed § 92.7(a) requires covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 coordinator (Section 1557 Coordinator) to coordinate their efforts to comply with and carry out the covered entity's responsibilities under Section 1557 and this part with regard to their health programs and activities. The 2016 Rule similarly required covered entities of this size to designate a compliance coordinator for Section 1557 at former § 92.7. We newly propose to permit covered entities to, as appropriate, assign one or more designees to carry out some of the responsibilities of the Section 1557 Coordinator. The 2016 Rule did not include this provision, and we include it here in recognition that some covered entities may want or need to spread the duties of the Section 1557 Coordinator over multiple staff. However, the Section 1557 Coordinator must retain ultimate oversight for ensuring coordination with the covered entity's compliance.

In 2020, the Department repealed the requirement for each covered entity with 15 or more employees to designate a Section 1557 Coordinator or ''designated employee,'' reasoning that to the extent that the implementing regulations for the referenced statutes ''have responsible employee and grievance procedures, they are sufficient for enforcement of Section 1557.'' [269] We believe that a designated Section 1557 Coordinator will help ensure covered entities comply with the requirements of Section 1557. Additionally, a designated Section 1557 Coordinator will better allow covered entities to resolve potential grievances as accurately and efficiently as possible, to the benefit of individuals seeking care as well as the covered entity.

The Department recognizes that covered entities with 15 or more employees may have retained their Section 1557 Coordinators required by the 2016 Rule even though the 2020 Rule does not require covered entities to do so. Under proposed § 92.7, those covered entities that have retained their Section 1557 Coordinators need not appoint a new one, though the existing Section 1557 Coordinator would be responsible for the responsibilities outlined in proposed paragraph (b).

The implementing regulations for Section 504 and Title IX require covered entities to designate a responsible employee to coordinate the covered entity's civil rights compliance, and the Title VI and Age Act regulations do not explicitly include such a requirement.[270] A covered entity that has already designated a responsible employee pursuant to the Section 504 or Title IX regulations may assign that individual to coordinate the covered entity's efforts to comply with Section 1557, provided that the scope of the individual's responsibilities is modified to include all prohibited bases of discrimination included in Section 1557 and other duties as required. Like the 2016 Rule, proposed § 92.7(a) standardizes the requirement for covered entities that employ more than 15 people to designate a Section 1557 Coordinator.

At proposed paragraph (b), we provide a list of responsibilities of the Section 1557 Coordinator. The 2016 Rule did not include a similar provision. The Department proposes to

[265] Gudeeshpal Randhawa et al., *Using Machine Translation in Clinical Practice,* 59 Can. Fam. Physician 328 (2013), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3625087/pdf/0590382.pdf.*

[266] *See, e.g.,* Dep't of Justice, Guidelines for the Enforcement of Title VI, Civil Rights Act of 1964, 28 CFR 50.3, pt. I.B.1 (listing various ''[p]ossibilities of judicial enforcement,'' including suits to enforce contractual assurances).

[267] *See* 85 FR 37160, 37162 (June 19, 2020).

[268] 45 CFR 86.3(a)–(b) (Title IX); § 84.6(a)–(b) (Section 504); § 91.48 (Age Act).

[269] 85 FR 37204.

[270] 45 CFR 84.7(a) (Section 504); § 86.8(a) (Title IX).

include a list of responsibilities to assist covered entities in developing a position description for the Section 1557 Coordinator and to identify the provisions over which Coordinators must have direct responsibility. Proposed responsibilities include, at a minimum, that the covered entity ensure that the Section 1557 Coordinator: (1) receives, reviews, and processes grievances filed under the grievance procedure as set forth in proposed § 92.8(c); (2) coordinates the covered entity's recordkeeping requirements as set forth in proposed § 92.8(c); (3) coordinates effective implementation of the covered entity's language access procedures as set forth in proposed § 92.8(d); (4) coordinates effective implementation of the covered entity's effective communication procedures as set forth in proposed § 92.8(e); (5) coordinates the covered entity's procedures for providing reasonable modifications for individuals with disabilities in accordance with proposed § 92.8(f); and (6) coordinates training of relevant employees as set forth in proposed § 92.9, including maintaining the required documentation.

We seek comment on this requirement, including whether OCR should require covered entities with fewer than 15 employees to designate a Section 1557 Coordinator and, if so, whether there should be a requisite number of employees or whether all covered entities should be required to designate a Section 1557 Coordinator. We are particularly interested in hearing from smaller covered entities who have a civil rights coordinator about whether they believe there is a benefit to having such a dedicated staff member, and any associated costs or burdens. We further seek comment on whether the enumeration of responsibilities of the Section 1557 Coordinator is beneficial and sufficiently comprehensive. We also seek comment on how the Department can support Section 1557 Coordinators, including through the provision of training, so that they understand their duties, the protections afforded by Section 1557, and the rationale for both.

Policies and Procedures (§ 92.8)

Proposed § 92.8 would require covered entities to develop and implement written policies and procedures that are designed to facilitate compliance with the requirements of this part. The Department recognizes that, taken alone, the implementing regulations for the statutes referenced in Section 1557 may require entities to undertake different processes depending on the alleged basis of discrimination.

This rulemaking provides for more consistency regardless of whether an allegation of discrimination in a covered health program or activity is based on race, color, national origin, sex, age, or disability—or some combination thereof. The 2020 Rule fails to account for claims of discrimination in health programs and activities that are alleged to have occurred based on multiple protected bases. The Department believes that establishing procedural requirements across nondiscrimination bases is important because it benefits the public and covered entities, and it streamlines OCR's enforcement scheme. For the public, providing consistent regulatory procedural requirements across nondiscrimination bases recognizes the potential for complaints alleging discrimination on multiple bases (*e.g.,* sex and race). Covered entities would gain clarity with respect to their regulatory procedural requirements without any confusion as to whether different provisions apply depending on the protected basis. For example, there are currently questions as to whether or not the 2020 Rule requires covered entities to have a responsible employee and grievance procedure to address issues of sex discrimination, or if that is only required to the extent that it would be required under Title IX (*i.e.,* whether the health program and activity must also be an education program or activity to trigger the requirement).

This proposed section would require each covered entity, in its health programs and activities, to adopt and implement a nondiscrimination policy, grievance procedures (for covered entities employing 15 or more persons), language access procedures, auxiliary aids and services procedures, and procedures for reasonable modifications for individuals with disabilities (collectively, ''Section 1557 Policies and Procedures''). We recognize that the covered entities vary significantly in size, nature of business, and location and accordingly recognize that each covered entity's Section 1557 Policies and Procedures may vary. OCR is committed to supporting covered entities as they develop policies and procedures and is planning to provide sample documents on the Department's website. Given the prevalence of covered entities with fewer than 15 employees that provide health care services to a significant volume of patients, the Department highly encourages such covered entities to implement Section 1557 Policies and Procedures based on the sample documents that will be available on the agency website. The Department underscores that covered entities with fewer than 15 employees would still be prohibited from discriminating in health programs and activities under Section 1557, even if those entities are not required to adopt grievance procedures, or to hire a Section 1557 Coordinator, under this proposed rulemaking.

The Department's goal is to address potential compliance issues and help resolve civil rights concerns at an early stage, avoiding the need for an OCR investigation. The Department has also heard from a range of stakeholders that it is important to include proactive measures to increase covered entities' knowledge of their responsibilities under Section 1557. The proposed complementary civil rights policies and procedures advance these objectives.

This proposed requirement is also informed by OCR's enforcement experience. It is common that, either during or following an investigation, OCR will enter into a voluntary resolution agreement with a covered entity that requires the adoption and implementation of nondiscrimination policies as well as procedures for providing auxiliary aids and services and reasonable modifications for individuals with disabilities, and language assistance services for LEP individuals.[271] OCR's resolution agreements require these interventions, in part, because our experience generally demonstrates that targeting such interventions at the underlying

[271] *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't of Justice, U.S. Dep't Health & Human Servs., Office for Civil Rights & William W. Backus Hosp. (2021), *https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/vra-between-doj-hhs-ocr-william-backus-hospital/index.html*; Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights & CHRISTUS Trinity Mother Frances Health Sys. (2020), *https://www.hhs.gov/sites/default/files/christus-vra.pdf*; Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights & Mid-Maryland Musculoskeletal Inst. (2019), *https://www.hhs.gov/sites/default/files/MMI-vra.pdf*; *https://www.hhs.gov/sites/default/files/uconn-vra.pdf*; Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights & Pa. Dep't of Human Servs. (2019), *https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/sites/default/files/hhs-padhs-vra.pdf*; Voluntary Resolution Agreement between U.S. Dep't of Justice, U.S. Dep't Health & Human Servs., Office for Civil Rights & Univ. of Vt. Med. Ctr. (2017), *https://www.hhs.gov/sites/default/files/uvmmc-vra.pdf*; Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights & Erie Cty. Dep't of Soc. Servs. (2016), *https://www.hhs.gov/sites/default/files/ecdss-vra-final.pdf*; Voluntary Resolution Agreement between U.S. Dep't of Justice, U.S. Dep't Health & Human Servs., Office for Civil Rights & St. Francis Hosp. & Med. Ctr. (2015), *https://www.hhs.gov/sites/default/files/stfrancishospital-vra.pdf*.

problems can result in covered entities being better positioned to prevent discriminatory conduct in the future.

Through the implementation of Section 1557 Policies and Procedures, a covered entity's employees will be better equipped to provide services in a nondiscriminatory manner. For example, an employee will be able to refer to the covered entity's official policy for providing LEP individuals with language assistance services; such policies will also be interpreted or translated as needed, and be available to an LEP individual or their representative. Overall, the covered entity's policies and procedures should bring consistency to the covered entity's health programs and activities and improve compliance.

Finally, we note that many health care providers have adopted policies and procedures required under OCR's existing civil rights authorities and therefore would only need to review and update such policies and procedures rather than creating them anew. For example, this provision is consistent with OCR's civil rights clearance process required of providers seeking initial certification or undergoing a change of ownership to be certified as a Medicare Part A provider by CMS.[272] In order to obtain a civil rights clearance, would-be Medicare Part A providers and businesses must have nondiscrimination policies and procedures, including: policies and procedures to identify and communicate orally and in writing with LEP individuals; policies and procedures to ensure effective communication for individuals with disabilities, including, where necessary, the provision of appropriate auxiliary aids and services; and a description of how Medicare providers and applicants make their program accessible to persons with disabilities, among other things.[273] This proposed provision would establish similar obligations. Under this proposed provision, covered entities may need to revise any pre-existing policies and procedures to ensure they, at minimum, include the proposed required content.

The Department acknowledges that requiring covered entities to develop and implement Section 1557 Policies and Procedures for their health programs and activities would be a departure from previous rulemakings, under which covered entities that implemented such policies and procedures did so voluntarily. However, the Department's enforcement and compliance assistance experience demonstrates that interventions such as implementing policies and procedures can result in covered entities being better positioned to prevent discriminatory conduct and to better avoid the risk of an employee providing services in a discriminatory manner. Thus, we are proposing the Section 1557 Policies and Procedures requirement because we believe that the lack of such a requirement leaves individuals more susceptible to discrimination and covered entities more susceptible to violations. Specifically, as noted above, we believe that such a proactive measure will more effectively increase covered entities' employees' knowledge of their responsibilities under Section 1557. The Department acknowledges that Section 1557 Policies and Procedures are not a panacea for eliminating discrimination in health care; however, we emphasize that our experience has indicated that implementing policies and procedures that are the same or similar to the proposed Section 1557 Policies and Procedures helps prevent future instances of discriminatory conduct.

Proposed paragraph (a) of this section requires covered entities to implement written Section 1557 Policies and Procedures. The policies and procedures must include an effective date and be reasonably designed, taking into account the size, complexity, and the type of health programs or activities undertaken by a covered entity, to ensure compliance with this part.

Proposed paragraph (b) requires each covered entity to implement a written nondiscrimination policy that, at minimum, provides the contact information for the Section 1557 Coordinator (if applicable) and states that the covered entity in its health programs and activities: does not unlawfully discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, and sex characteristics), age, or disability; and provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with Section 1557 or this part.

Proposed paragraph (c) addresses the requirements for covered entities with 15 or more employees with regard to grievance procedures and recordkeeping in their health programs and activities, including ensuring that the grievance procedure is accessible to LEP individuals and individuals with disabilities.

In proposed paragraph (c)(1), OCR is proposing to require that covered entities with more than 15 employees establish written civil rights grievance procedures. This is similar to the 2016 Rule at former § 92.7, except that we propose to include a record retention requirement. The 2020 Rule repealed former § 92.7 and provided that certain covered entities need only have a grievance procedure to the extent the referenced statutes require it.[274] We believe that the requirement in proposed paragraph (c)(1) will restore consistency of requirements for covered entities that existed under former § 92.7. It is also responsive to data related to improving health care visits for historically marginalized communities, which indicate that a majority of patients in these communities desire a method for submitting grievances to health care providers so that the providers can address the patients' problems.[275] Though the referenced data did not identify whether patients desired a mechanism to submit discrimination grievances specifically, the data support the supposition that, for patients of color, trust in their health care providers would increase if these patients could voice their concerns directly to their health care providers, thus, improving these patients' overall health care experiences. Accordingly, the Department's proposed § 92.8(c) provides a mechanism for patients to raise allegations of discrimination directly to their respective health care providers. We expect covered entities to tailor the sample grievance procedure to fit their different needs for flexibility, efficiency, and cost effectiveness.

At paragraph (c)(2), we propose that a covered entity must retain records related to grievances filed with it that allege discrimination on the basis of race, color, national origin, sex, age, or disability in its health programs and activities for no less than three (3) years from the date of the filing of the

[272] *See Civil Rights Clearance for Medicare Provider Applicants,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/index.html* (last updated Oct. 26, 2021).

[273] *See Technical Assistance for Medicare Providers and Applicants,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/technical-assistance/index.html* (last updated Oct. 27, 2021).

[274] 85 FR 37160, 37204 (Jun. 19, 2020) (''To the extent that [the referenced statutes'] implementing regulations have . . . grievance procedures, they are sufficient for enforcement of Section 1557.'').

[275] Leslie Read et al., The Deloitte Ctr. for Health Solutions, Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?, p. 3 (2021) (''62% [of surveyed people of color] want their local hospitals to ensure patients have a voice to relay their experiences and take action to address their problems.''), *https://www2.deloitte.com/content/dam/insights/articles/US164518_CHS-Equity-trust/DI_Rebuilding-trust-in-healthcare.pdf.*

grievance. The records must include the grievance; the name and contact information of the complainant (if provided by the complainant); the alleged discriminatory action and alleged basis (or bases) of discrimination; the date the grievance was filed; the grievance resolution; and any other pertinent information. Pertinent information includes, to the extent relevant to a particular complaint, information related to the complainant's national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, or sex characteristics), etc.

Through its enforcement experience, OCR has found that obtaining records of past grievances from covered entities is an important and informative component of a thorough investigation, as it assists OCR in identifying potential patterns or practices of discrimination that may not otherwise be apparent while reviewing a single OCR discrimination complaint. For example, if OCR receives a single discrimination complaint from a person giving birth alleging discrimination on the basis of race, OCR could review the grievances submitted to a covered entity to identify the presence or absence of any potential patterns of discrimination against people giving birth on the basis of race. Without a requirement to retain grievances for a period of time, it is more difficult for OCR to identify potential patterns or practices of discrimination. This requirement will assist OCR not only in identifying the scope of concern, but also in crafting appropriate technical assistance and complaint resolutions.

OCR understands that retaining grievances for a specified period of time is already the practice of some covered entities. This requirement seeks to make the practice more consistent, thereby allowing OCR to better identify potential patterns or practices of discrimination during complaint investigations and compliance reviews. Having access to discrimination complaints over a period of time will also allow covered entities to be proactive in identifying potential patterns or practices of discrimination, which will allow them to take corrective actions, if necessary, before a complaint is filed with OCR. We believe the three-year record retention requirement strikes the right balance between covered entities' burden concerns and the need for access to this vital information. However, while we propose to require records to be kept for three (3) years, nothing in the proposed rule will prevent covered entities from keeping their records for a longer period of time if the recipient wishes or due to other legal obligations.[276]

Proposed paragraph (c)(3) requires that a covered entity keep confidential the identity of an individual who has filed a grievance, except as required by law or to the extent necessary to carry out the purposes of this proposed regulation, including the conduct of any investigation.

We seek comment on the record retention requirement, particularly with regard to patient privacy concerns or concerns regarding potentially unauthorized use of information included in such records. We seek comment on best practices for record retention of grievance procedures, including strategies for ensuring patient privacy.

Rather than requiring health programs and activities of the Department to adopt separate grievance procedures, the 2016 Rule provided that, for the Department, the procedures for addressing complaints of discrimination under Section 1557 would be deemed the required grievance procedures under this section. We decline to reinstate this approach, as individuals and the Department's health programs and activities can also benefit from a process for covered entities to address any potential compliance issues at an earlier stage and in a less formal manner than an OCR investigation. However, individuals may opt not to use a health program or activity's grievance procedure and may elect to file a complaint with OCR at any time, regardless of whether the health program or activity is conducted by a recipient, the Department, or a Title I entity.

Proposed paragraph (d) requires covered entities to develop and implement written language access procedures to support compliance with requirements to take reasonable steps to provide meaningful access to LEP individuals in their health programs and activities under proposed § 92.201. Given existing requirements to provide language assistance to LEP individuals under Title VI and Section 1557, informed by the Department's ''2003 Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons'' (HHS LEP Guidance),[277] we anticipate that some covered entities may have already implemented policies and procedures akin to this requirement. Additionally, Federal agencies have been required to have language access procedures since 2000, as provided for in E.O. 13166,[278] and the Department itself has a Language Access Plan.[279] This requirement is also consistent with the civil rights clearance process required for Medicare Part A providers, which requires policies and procedures to identify and communicate orally and in writing with LEP individuals.[280]

We propose that, at a minimum, a covered entity's language access procedures must include information detailing the contact information for the Section 1557 Coordinator (if applicable); how an employee identifies whether an individual is LEP; how an employee obtains the services of qualified interpreters and translators the covered entity uses to communicate with LEP individuals; the names of any qualified bilingual or multilingual staff members; and a list and the location of any electronic and written translated materials the covered entity has, the languages they are translated into, and the publication date. We note that covered entities have a duty to translate that extends beyond those documents that have already been translated at the time this list is made, and the list should be updated periodically.

Proposed paragraph (e) requires covered entities to develop and implement written effective communication procedures to support compliance with requirements to take appropriate steps to ensure that communications in their health programs and activities with individuals with disabilities are as effective as communications with individuals without disabilities under proposed § 92.202. We propose that, at a minimum, a covered entity's effective communication procedures must include the contact information for the Section 1557 Coordinator (if applicable); how an employee obtains the services of qualified interpreters the covered entity uses to communicate with individuals with disabilities; the names of any qualified interpreter staff members; and how to access appropriate auxiliary aids and services that are necessary for

[276] For example, the Department of Education Title IX regulation requires recipients to keep records related to Title IX sexual harassment grievances and investigations for a period of seven (7) years. 34 CFR 106.45(b)(10).

[277] 68 FR 47311, 47316 (Aug. 8, 2003).

[278] 65 FR 50121 (Aug. 16, 2000).

[279] U.S. Dep't of Health & Human Servs., Language Access Plan (2013), *https://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf*.

[280] *Technical Assistance for Medicare Providers and Applicants,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/technical-assistance/index.html* (last updated Oct. 27, 2021).

effective communication. This provision is similarly consistent with the civil rights clearance process required for Medicare Part A providers, which requires policies and procedures to ensure effective communication for individuals with disabilities, including, where appropriate, the provision of auxiliary aids and services.[281]

Proposed paragraph (f) requires covered entities to develop and implement written procedures for making reasonable modifications to their policies, practices, or procedures that allow individuals with disabilities equal opportunity to participate in their health programs and activities as required under proposed § 92.205. As proposed, a covered entity's reasonable modification procedures must, at a minimum, include contact information for the covered entity's Section 1557 Coordinator (if applicable); describe the covered entity's process for responding to requests from individuals with disabilities for changes, exceptions, or adjustments to a rule, policy, practice, or service of the covered entity; and the process for determining whether making the modification would fundamentally alter the nature of the service, program, or activity, including identifying an alternative modification that does not result in a fundamental alteration to ensure the individual with a disability receives the benefits or services in question.

We note that the failure to request a reasonable modification does not always excuse the covered entity from providing a reasonable modification to avoid discrimination on the basis of disability, as long as it does not result in a fundamental alteration. For example, when a covered entity had knowledge of an individual's disability and needs, or when an individual's disability and needs are obvious, a covered entity must provide modifications in the absence of a request.[282]

Proposed paragraph (g) provides that a covered entity may combine the content of the policies and procedures required by this provision with any policies and procedures pursuant to other civil rights statutory protections if they clearly comply with Section 1557 and the provisions in this part.

The Department encourages covered entities to include additional information in their Section 1557 Policies and Procedures to provide employees the means to ensure individuals are able to access their health programs and activities free from discrimination. For example, covered entities may consider including information in their respective Section 1557 Policies and Procedures regarding service animals, as well as maintaining civil rights protections during public health emergencies.

We seek comment on this proposed provision and whether there may be alternative measures that the Department should consider to proactively prevent discrimination, and whether they would be more or less burdensome than what is proposed. We would particularly welcome comments from covered entities concerning their experiences under voluntary resolution agreements with OCR requiring them to adopt policies and procedures. We also invite comment from all covered entities that have previously implemented or are currently implementing a nondiscrimination policy, grievance procedures, language access procedures, effective communication procedures, or reasonable modification procedures; consumers who interact with covered health programs and activities; and community-based organizations that work with LEP individuals and individuals with disabilities. We also seek comment on whether covered entities employing less than 15 people should be required to have a grievance procedure, including the benefits for a less formal resolution process.

Training (§ 92.9)

To ensure that covered entities implement Section 1557 Policies and Procedures in accordance with proposed § 92.8, proposed § 92.9 requires covered entities to train relevant employees in their health programs and activities on their Section 1557 Policies and Procedures. This proposed section, coupled with § 92.8, is designed to help covered entities and their employees take measures to prevent discrimination by ensuring that staff are knowledgeable about the nondiscrimination policy, grievance procedures, and processes by which to obtain language assistance services for LEP individuals and to ensure effective communication with and provide reasonable modifications for individuals with disabilities.

Proposed paragraph (a) provides a general requirement that covered entities train relevant employees of their health programs and activities on the Section 1557 Policies and Procedures required by proposed § 92.8. Given the diversity of entities covered by this part, the Department is not prescribing the specific training methods a covered entity must use or the nature of a covered entity's training program. The Department notes, however, that the more thoroughly a covered entity trains its staff on its Section 1557 Policies and Procedures, the more likely it is that the covered entity will successfully provide services to individuals in a nondiscriminatory manner and avoid potential liability for violations of Section 1557 and this part.

Further, this provision takes into consideration potential burdens on covered entities by requiring that only relevant staff (including, but not limited to, the Section 1557 Coordinator, if applicable) be trained, rather than requiring all staff to be trained. The Department anticipates that relevant health program and activity staff will include those involved in client and patient interactions, as well as those involved with drafting, approving, and funding policies and procedures for compliance with this part. However, such aspects of training required by this section are left to the discretion of the covered entity. The proposed approach, which requires training only on the covered entity's Section 1557 Policies and Procedures, is efficient, provides practical benefits based on each covered entity's unique circumstances, and is less resource intensive than requiring covered entities to train relevant staff on all of the regulatory requirements for Section 1557's underlying statutes.

Similar to the proposal to require Section 1557 Policies and Procedures, the Department believes in the importance of proactive measures to prevent and mitigate the potential for discriminatory conduct in covered health programs and activities. That is why the Department proposes to require training in this rulemaking. OCR provides public education and outreach and has found it to be an effective means to ensure covered entities are complying with their respective Federal civil rights obligations. Just as OCR's proactive public education and outreach efforts yield compliance benefits, based on the Department's enforcement and compliance assistance experience we believe that covered entities' proactive Section 1557 Policies and Procedures, coupled with employee training, will

[281] *Technical Assistance for Medicare Providers and Applicants,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/technical-assistance/index.html* (last updated Oct. 27, 2021).

[282] *See, e.g., Greer* v. *Richardson Indep. Sch. Dist.,* 472 F. App'x 287, 296 (5th Cir. 2012) (holding that a ''failure to expressly 'request' an accommodation is not fatal to an ADA claim where the defendant otherwise had knowledge of the individual's disability and needs but took no action''); *Duvall* v. *Cty. of Kitsap,* 260 F.3d 1124, 1139 (9th Cir. 2001) (''When the plaintiff has alerted the public entity to his need for accommodation (or where the need for accommodation is obvious . . .), the public entity is on notice that an accommodation is required . . .'').

yield compliance benefits as well as improved health outcomes.[283]

Federal agency technical assistance materials on language access consistently highlight the important role training plays in delivering services effectively. For example, CMS' ''Guide to Developing a Language Access Plan'' dedicates an entire section to advising organizations about the importance of training.[284] The Guide provides, in part, that an organization's training should focus on the organizations' policies and procedures related to providing language assistance services. Similarly, a DOJ assessment and planning tool for federally conducted and federally assisted programs included ''training staff on policies and procedures'' as one of the key six steps for developing an effective language access policy.[285] DOJ's tool provides that ''[t]raining should explain how staff can identify the language needs of an LEP individual, access and provide the necessary language assistance services, work with interpreters, request document translations, and track the use of language assistance services.'' [286]

The Department believes that a staff training requirement will increase the likelihood that covered entities are prepared to best meet the communication needs of LEP individuals and individuals with disabilities, avoiding potentially critical delays or denials of care. This is particularly salient as the nation addresses the COVID–19 pandemic and works to prepare for future public health emergencies. As described above, the COVID–19 pandemic exposed barriers to accessing health care for historically marginalized populations, including challenges related to providing testing and vaccination services in a way that provides meaningful access to LEP individuals and is accessible to individuals with disabilities. For example, many covered entities required individuals to register on a website or through an online portal in order to obtain a COVID–19 test or vaccine. Websites and portals often failed to include non-English registration instructions,[287] and some have been inaccessible to individuals with disabilities.[288]

We have previously noted that, when necessary, OCR enters into voluntary resolution agreements with covered entities to resolve concerns about noncompliance with Federal civil rights laws, including Section 1557.[289] These voluntary resolution agreements routinely require covered entities to develop policies and procedures and provide employee training on their policies and procedures because such actions promote compliance with Federal civil rights laws. OCR believes that the development and implementation of, and training on, such policies are likely to reduce discriminatory actions from occurring in the future and reduce the need for voluntary resolution agreements.

Proposed paragraph (a) provides a general requirement that covered entities train relevant employees of their health programs and activities on the civil rights policies and procedures required by proposed § 92.8.

Proposed paragraph (b) specifies when covered entities must train relevant employees on their Section 1557 Policies and Procedures. We consider relevant employees to be those who directly encounter or interact with individuals such as patients, clients, and members of the public. Employees are also considered relevant when they make decisions regarding the services individuals seek from a covered entity's health programs and activities. Under paragraph (b)(1) covered entities would be required to train existing relevant employees on their Section 1557 Policies and Procedures as soon as practicable, but no later than one (1) year after the effective date of the Final Rule. Proposed paragraph (b)(2) proposes that covered entities train new relevant employees within a reasonable period of time after they join a covered entity's workforce.

In paragraph (b)(3), we propose to require covered entities to train relevant employees whose roles are affected by material changes to the covered entity's Section 1557 Policies and Procedures. Examples of material changes may include new contact information for a covered entity's Section 1557 Coordinator (if applicable), changing from one qualified interpreter service provider to another, acquiring or discontinuing the use of certain auxiliary aids and services, such as in response to changing technology, or substantive changes to the covered entity's process for ensuring effective communication or for providing language assistance services. Similar to paragraph (b)(2), paragraph (b)(3) would require covered entities to train employees within a reasonable time after a material change has been made. Nothing in the proposed provision prohibits covered entities from training their employees on Section 1557 Policies and Procedures more frequently. For example, covered entities may include such training in the existing annual or quarterly training programs that they require their employees to complete.

Proposed paragraph (c) requires covered entities to contemporaneously document their employees' completion of the training required by this section

[283] *See, e.g.,* John S. Lord, Jr., *Health Care Providers: It's Not Just Employee Discrimination Claims—Patients Can Have Discrimination Claims Too,* Nat'l L. Rev. (Feb. 8, 2022) (recommending ''perioding compliance reviews and up-to-date trainings'' on civil rights nondiscrimination requirements to ''help prevent and defend'' against patient discrimination claims), *https://www.natlawreview.com/article/health-care-providers-it-s-not-just-employee-discrimination-claims-patients-can-have.*

[284] U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Guide to Developing a Language Access Plan, p. 9, *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan-508.pdf.*

[285] U.S. Dep't of Justice, Language Access Assessment and Planning Tool for Federally Conducted and Federally Assisted Programs, p. 6 (2011), *https://www.lep.gov/sites/lep/files/resources/2011_Language_Access_Assessment_and_Planning_Tool.pdf.*

[286] *Id.*

[287] Joseph R. Fuchs et al., *Older Adults with Limited English Proficiency Need Equitable COVID–19 Vaccine Access*, 69 J. Am. Geriatr. Soc'y. 888, 889 (2021), *https://agsjournals.onlinelibrary.wiley.com/doi/10.1111/jgs.17069*; *Rachana Pradham, 'Press 1 for English': Vaccination Sign-Ups Prove Daunting for Speakers of Other Languages,* Kaiser Health News (Mar. 23, 2021), *https://khn.org/news/article/press-1-for-english-vaccination-sign-ups-prove-daunting-for-speakers-of-other-languages/.*

[288] Press release, U.S. Dep't of Justice, Justice Department Secures Settlement with Rite Aid Corporation to Make Its Online Covid-19 Vaccine Portal Accessible to Individuals with Disabilities (Nov. 1, 2021), *https://www.justice.gov/usao-mdpa/pr/justice-department-secures-settlement-rite-aid-corporation-make-its-online-covid-19*; *Press release,* U.S. Dep't of Justice, Justice Department Secures Agreement with Hy-Vee Supermarket Chain to Make Online COVID–19 Vaccine Registration Accessible for People with Disabilities (Dec. 1, 2021), *https://www.justice.gov/opa/pr/justice-department-secures-agreement-hy-vee-supermarket-chain-make-online-covid-19-vaccine*; Lauren Weber & Hannah Recht, *Covid Vaccine websites Violate Disability Laws, Create Inequity for the Blind,* Kaiser Health News (Feb. 25, 2021), *https://khn.org/news/article/covid-vaccine-websites-violate-disability-laws-create-inequity-for-the-blind/*; Haley Messenger, *Blind Americans Face Roadblocks Booking Online Vaccine Appointments,* NBC News (Mar. 13, 2021, 6:02 a.m.), *https://www.nbcnews.com/business/consumer/blind-americans-face-roadblocks-booking-online-vaccine-appointments-n1260954*; *Fixing the Problem of Inaccessible Information from the Beginning,* Equidox, *https://equidox.co/blog/fixing-the-problem-of-inaccessible-covid-19-information/* (last visited June 15, 2022); Elise Young, *Vaccine Rollout Leaves Behind the Blind, Paralyzed, Autistic,* Bloomberg (Mar. 18, 2021, 10:25 a.m.), *https://www.bloomberg.com/news/articles/2021-03-18/disabled-citizens-left-behind-in-u-s-push-to-overcome-pandemic*; Maggie Vaughn, *Vaccine Registration websites: Inaccessible to the Blind,* Dubbot: DubBlog (Mar. 10, 2021), *https://dubbot.com/dubblog/2021/vaccine-registration-websites-inaccessibile-to-the-blind.html.*

[289] *See Recent Civil Rights Resolution Agreements & Compliance Reviews,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/index.html* (last updated June 15, 2022); *see also supra* note 271.

in written or electronic form and maintain said documentation for no less than three (3) calendar years.

We note that neither the 2016 Rule nor the 2020 Rule included a training requirement, though we are aware that many covered entities already have civil rights trainings for their employees that could be modified to comply with this proposed provision. We seek comment on the experiences of covered entities in implementing training such as that required by proposed § 92.9, examples of where training made a difference in compliance, the timing of required training, whether covered entities would like the flexibility to include this required training as part of its existing annual compliance training, what types of changes would constitute a material change such that a covered entity would need to retrain staff, and the amount of time for which training records must be retained. We also seek general comment on this proposal, including the effectiveness of civil rights training programs, the benefits experienced by covered entity staff and the people they serve, as well as the costs associated with the proposed training requirements.

We further seek comment on whether the Section 1557 Policies and Procedures requirements and training requirements may increase the likelihood of compliance with the substantive legal requirements of Section 1557.

Notice of Nondiscrimination (§ 92.10)

Proposed § 92.10 requires each covered entity to provide a notice of nondiscrimination, relating to its health programs and activities, to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public. Notice can be provided through written translations or in-language recorded audio or video clips.

The 2016 Rule required covered entities to include a nondiscrimination notice and set of taglines (*i.e.,* a short non-English statement in appropriate languages indicating the availability of language assistance services) in all ''significant publications or significant communications . . . which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual'' in conspicuous physical locations and online.[290] The 2016 Rule included a separate provision for ''small-sized'' significant publications communications.[291] This provision required covered entities to include a notice statement in lieu of the full notice, on small-sized significant publications and significant communications like postcards and tri-fold brochures.[292]

The 2016 Rule received criticism for failing to provide a definition of ''significant publications or significant communications,'' though it provided some examples of what would be considered ''significant.'' The Department also received substantial feedback regarding the financial burden imposed by the notice and tagline requirements. Citing these concerns, the 2020 Rule repealed the 2016 Rule's provisions on notices and taglines in their entirety.[293]

The Department has reviewed concerns raised in response to the 2016 Rule requirements, as well as those raised in response to the removal of the notice and tagline requirements in the 2020 Rule. Although we acknowledge the additional responsibilities placed on covered entities through the 2016 Rule requirements, we believe that the 2020 Rule does not adequately consider some of the adverse consequences that individuals incur or the burdens that the health care system faces without these notice provisions.[294] Therefore, the Department has concluded that it should not have eliminated these provisions in their entirety. To ensure clarity and reduce confusion, this proposed rule will address the notice of nondiscrimination and notice of availability of language assistance services and auxiliary aids and services in separate sections.

Proposed § 92.10(a) requires covered entities to provide a notice of nondiscrimination, relating to their health programs and activities, to participants, beneficiaries, enrollees, and applicants of their health programs and activities, and to members of the public. Proposed paragraph (a)(1) provides the required contents of the notice of nondiscrimination, including that (i) the covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, or sex characteristics), age, or disability in its health programs or activities; (ii) the covered entity provides reasonable modifications for individuals with disabilities, and appropriate auxiliary aids and services, including qualified interpreters, for individuals with disabilities and information in alternate formats, such as braille or large print, free of charge and in a timely manner, when such modifications or aids and services are necessary to ensure accessibility and equal opportunity to participate to individuals with disabilities; (iii) the covered entity provides language assistance services, including electronic and written translated documents and oral interpretation free of charge and in a timely manner, when such services are necessary to provide meaningful access to a limited English proficient individual; (iv) how to obtain from the covered entity the reasonable modifications, auxiliary aids and services, and language assistance services in paragraphs (a)(1)(ii) and (iii) of this section; (v) the contact information for the covered entity's Section 1557 Coordinator designated pursuant to § 92.7 of this part (if applicable); (vi) the availability of the covered entity's grievance procedure pursuant to § 92.8(c) of this part and how to file a grievance (if applicable); (vii) details on how to file a discrimination complaint with HHS' Office for Civil Rights; and (viii) how to access the covered entity's website, if it has one, that provides the information required under paragraph (a)(1) of this section. OCR is proposing to require a parenthetical for national origin discrimination, to include limited English proficiency and primary language, to clarify for the public that these are prohibited forms of discrimination. For the same reason, a parenthetical would be required for sex discrimination, to include pregnancy, sexual orientation, gender identity, or sex characteristics.

Proposed § 92.10(a)(2) would provide specific information on when and where covered entities must provide the notice of nondiscrimination. Rather than requiring entities to include the notice in ''significant'' communications, we propose that covered entities provide the notice on an annual basis and upon request. Similar to the 2016 Rule requirements, we propose that the notice also be placed at a conspicuous location on the covered entity's health program or activity website,[295] if it has

[290] 81 FR 31375, 31396 (May 18, 2016).

[291] Former 45 CFR 92.8(g)(1).

[292] *Id.*

[293] 85 FR 37160, 37161, 37176, 37228 (June 19, 2020).

[294] *See, e.g.,* Nat'l Council of Asian Pacific Ams., Comment on Section 1557 NPRM, pp. 3–7 (Aug. 13, 2019), *https://www.regulations.gov/comment/HHS–OCR–2019–0007–145953.*

[295] For more information about improving access to public websites for LEP individuals, *see* U.S. Dep't of Justice, Title VI Interagency Working Group, Improving Access to Public websites and Digital Services for Limited English Proficient (LEP) Persons (Dec. 2021), *https://www.lep.gov/sites/lep/*

one, and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice. These requirements would pose a relatively low-cost burden for covered entities while ensuring information regarding the covered entity's civil rights obligations is provided in locations that are highly visible and visited by participants and members of the public.

Paragraph (b) proposes that a covered entity may combine the content of the notice required by paragraph (a) of this section with the notices required by Title VI, Section 504, Title IX, and the Age Act implementing regulations [296] if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part and meets the requirements outlined in proposed paragraph (a)(1).

In drafting these proposed notice provisions, the Department considered alternative approaches such as requiring covered entities to provide notices at every encounter with a participant or beneficiary or simply adopting the approach in the 2016 Rule. The Department decided against these approaches, and believes the proposed provisions emphasize the importance of notifying individuals of their civil rights and makes clear the requirements for notifying individuals about important civil rights requirements. Further, we believe this proposal addresses the burdens raised by covered entities in response to the 2016 Rule notice requirements by providing specific occurrences (annual basis and upon request) and locations (conspicuous location on website and prominent physical location) for when and where the notice must be provided rather than the ambiguity caused by the 2016 Rule.

We seek comment on whether the notice of nondiscrimination requirement as proposed is practical, likely to be effective, and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the content of the notice and requirements regarding when and where covered entities must provide the notice. In particular, we seek comment on the best ways to provide an accessible initial notice to individuals who may require auxiliary aids and services for their disabilities and the best way in which to provide the notice in a manner accessible to LEP individuals. The Department is also interested in hearing from covered entities regarding whether they are still following the 2016 notice requirement, and the potential burdens and costs of what is proposed here.

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

Proposed § 92.11 requires covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities (''Notice of Availability''). This provision is similar to the ''tagline'' requirement found at former § 92.8 in the 2016 Rule, but with additional information required to be included in the notice. The 2016 Rule required covered entities to provide ''taglines,'' short statements written in non-English languages that indicate the availability of language assistance services free of charge, in a variety of languages and communications.[297] The Department has opted not to use the term ''tagline'' in this rule because this provision also now requires a notice of the availability of auxiliary aids and services.

The 2016 Rule required covered entities to include ''taglines'' in at least the top 15 languages spoken by LEP individuals in the relevant state or states in significant publications and communications and at various locations.[298] To reduce the administrative burden on covered entities, OCR translated these statements into 64 languages and made the translated statements available to covered entities.[299]

The 2020 Rule repealed this provision, citing costs, confusion, and waste, but stated that covered entities are still required ''to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity.'' [300] Commenters argued the 2019 NPRM's Regulatory Impact Analysis (RIA) labeled the impact on LEP individuals of eliminating notice and tagline requirements as negligible without providing an evidentiary basis [301] and failed to address the costs beneficiaries would face without these provisions and the additional costs to the health care system that could result.[302] We now believe that in finalizing the 2020 Rule absent any ''tagline'' requirement, the Department did not adequately weigh the concerns raised by commenters, including the costs individuals incur or the burdens the health care system would face without these requirements.[303]

Commenters specifically argued that eliminating ''tagline'' provisions would result in fewer safeguards that minimize health care risks LEP individuals face in the health care system, including avoidable hospital readmissions, lower rates of outpatient follow up, limited use of preventive services, poor medication adherence, and lack of understanding discharge instructions.[304] According to commenters, these impacts could lead to higher costs to the health care system, as LEP individuals are more likely to experience medical errors due to communication barriers. The availability of language assistance services, on the other hand, is associated with fewer readmission rates and fewer malpractice claims.[305]

Several organizations have sued the Department for repealing the notice and tagline provisions of the 2016 Rule. The lawsuits detail the costs of repealing these requirements. In the *Whitman-Walker* case, the plaintiffs, organizations providing and advocating for health care services, and individual health care professionals, alleged that the removed provisions are critical to ensuring meaningful access to care.[306] The plaintiffs further argued that removing the 2016 Rule's tagline provisions, ''burden[s] private health care and individual provider plaintiffs, as well as members of health professional association plaintiffs, because patients will come to them sicker due to inadequate care elsewhere, and more people may come to them because their LEP services will remain robust.'' [307] The plaintiffs also alleged that eliminating the notice provisions would make it more difficult for patients ''to understand their health care rights, communicate with doctors and other health care workers, and navigate complex insurance and medical

files/media/document/2021-12/2021_12_07_website_Language_Access_Guide_508.pdf.

[296] 45 CFR 80.6(d) (Title VI); § 84.8 (Section 504, federally assisted); § 85.12 (federally conducted); § 86.9 (Title IX); § 91.32 (Age Act).

[297] Former 45 CFR 92.8.

[298] *Id.* § 92.8(d)(1).

[299] 81 FR 31453.

[300] *See* 85 FR 37160, 37176, 37228, 37241 (June 19, 2020).

[301] *See id.* at 37204.

[302] *See* Nat'l Council of Asian Pacific Ams., *supra* note 294, at pp. 3–7; *see also* 85 FR 37233.

[303] *See supra* note 302.

[304] *See* Nat'l Women's Law Ctr., Comment on Section 1557 NPRM, p. 21 (Aug. 13, 2019), *https://www.regulations.gov/comment/HHS-OCR-2019-0007-149018.*

[305] *See* Nat'l P'ship for Women & Families, Comment on Section 1557 NPRM, p. 16 (Aug. 13, 2019) (citing to Quan K. Lynch, Nat'l Health Law Program, The High Costs of Language Barriers in Medical Malpractice, p. 18 (2010)), *https://www.regulations.gov/comment/HHS-OCR-2019-0007-137897.*

[306] *Whitman-Walker* Compl., supra note 205, at p. 67–68.

[307] *Id.* at p. 68.

documents with specialized terminology, and cause an increase in patients who will delay or not seek care at all.'' [308] In *Chinatown Services Center* v. *U.S. Department of Health & Human Services,* the plaintiffs, community-based organizations that serve older LEP adults, similarly alleged that elimination of the notice and tagline requirements of the 2016 Rule undermines access to health care, and that the elimination was arbitrary and capricious because HHS did not consider alternatives to repealing these protections.[309] The *Chinatown Service Center* plaintiffs alleged the 2020 Rule fails to adequately consider the confusion caused by the removal of taglines, the impact of the rule change on access to care and treatment, individuals' reliance on taglines, and frustration with difficulty accessing health care.[310] The complaint alleges that ''without notice of their rights, LEP older adults remain in the dark as to their right to free interpreter services at a medical appointment or what they can do when providers wrongly require LEP individuals to rely on unqualified informal or family-member interpreters.'' [311]

The Department has also heard from covered entities that they are committed to providing LEP individuals with language assistance services but recommend that the Department require covered entities to provide language assistance services in a manner that does not overwhelm enrollees with redundant paperwork that may be unnecessary, repetitive, or wasteful.[312]

After considering concerns raised through litigation, stakeholder feedback, and language access complaints OCR continues to receive, we have determined that the 2020 Rule's approach in eliminating these provisions in their entirety is unnecessary and counterproductive. We believe that the benefits of meaningful access to LEP individuals, through notice of the availability of language access services, outweigh the costs of implementing the changes set forth in this NPRM. The 2020 Rule creates uncertainty and confusion concerning when language assistance services must be provided, resulting in higher risk for covered entities while rendering Section 1557 less effective at combatting discrimination experienced by LEP individuals. The Department believes that the provisions set forth in this NPRM would help restore consistency in language assistance procedural requirements and provide certainty to covered entities and consumers about what covered entities' obligations are and what rights consumers have.

The proposed reinstatement of in-language notices is also intended to help alleviate burdens on covered entities who primarily serve LEP populations. LEP individuals often rely on community-based organizations as the first line of support when they are unable to access other systems due to language barriers. While we recognize that this reported increase coincides with the COVID–19 pandemic, we also believe it highlights the importance now, more than ever, of providing notice of the availability of language assistance services in health programs and activities. Additionally, we believe having these services in place now will help covered entities be better prepared to serve LEP individuals during any future public health emergencies that may arise.

In addition, several commenters to the 2019 NPRM indicated that removing the 2016 Rule's tagline provisions would contribute to health disparities. For example, the National Women's Law Center referenced a 2018 poll, which said approximately 6 in 10 Latino adults reported having trouble communicating with their providers due to language or cultural barriers.[313] As a result, the poll reported that Spanish-speaking LEP individuals are more likely to report experiencing worse health outcomes than Latino individuals who are monolingual in English or bilingual in English and Spanish.[314] Although the 2020 Rule removed the requirement that covered entities include ''taglines'' in the top 15 languages spoken by LEP individuals in their state, it maintained the requirement that covered entities provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered health program or activity. Yet the 2020 Rule provides limited guidance to covered entities and consumers on what covered entities' obligations are and what consumers' rights are. Covered entities remain without clear guidance as to when in-language taglines must be included to help LEP individuals understand that language services are available and how to access them. OCR continues to receive language access complaints that raise concerns about entities not providing sufficient taglines. The proposed ''Notice of Availability'' requirement, analogous to the 2016 Rule ''tagline'' requirement, removes existing ambiguity for covered entities and would result in increased access to health programs and activities for LEP individuals.

While the 2020 Rule preamble raised concerns about cost and waste, we believe it failed to strike the right balance by eliminating these important provisions altogether given the considerations discussed above. With proposed § 92.11, we seek to be responsive to industry concerns regarding excessive costs and other potential burdens to covered entities, while balancing the importance of providing LEP individuals notice of the availability of language assistance services to eliminate barriers to accessing quality health care. In this new provision, we also propose to require the Notice of Availability to include a statement regarding the availability of appropriate auxiliary aids and services to reduce barriers to access for individuals with disabilities.

Proposed paragraph (a) requires a covered entity to provide a notice that, at minimum, states that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge in its health programs and activities, when necessary for compliance with Section 1557 or this part. This notice must be provided to participants, beneficiaries, enrollees, and applicants of the covered entity's health program or activity, and members of the public. Notice can be provided through written translations or recorded audio or video clips.

Proposed paragraph (b) requires the Notice of Availability to be provided in English and at least the 15 most common languages spoken by LEP individuals of the relevant state or states, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications. This standard ensures that a significant proportion of each state's particular LEP population is receiving key information in the appropriate language. While the standard of providing the statement in these ''top 15'' languages is the same as that required by the 2016 Rule, we attempt to alleviate burdens here by proposing a list of the relevant materials in which the Notice of Availability must be included and providing options for covered entities to allow individuals to ''opt out'' of receipt of the Notice of

[308] *Id.* at p. 28.

[309] Compl., *Chinatown Serv. Ctr.* v. *U.S. Dep't of Health & Human Servs.*, No. 1:21–cv–00331, pp. 23, 35 (D.D.C. Feb. 5, 2021), ECF No. 1 [hereinafter *Chinatown Serv. Ctr.* Compl.].

[310] *Id.* at p. 21.

[311] *Id.* at p. 2.

[312] AHIP Recommendations for 1557 Notice and Tagline Requirements, p. 1 (Nov. 1, 2021). The document will be attached to the docket of this proposed rule as a supplemental material at *federalregister.gov.*

[313] Nat'l Women's Law Ctr., *supra* note 304, at p. 21.

[314] *Id.*

Availability or to provide communication to individuals in their primary language in lieu of a Notice of Availability. As in 2016, OCR will provide a sample Notice of Availability for covered entities to use, as well as the 15 most common non-English languages spoken by LEP individuals for each state and territory.

The Department considered including a population threshold after consulting the Department of Agriculture's Supplemental Food and Nutrition regulation, which includes requirements prescribed by the Food Stamp Act [315] to translate materials in non-English languages.[316] The Department declines to include the adoption of a population threshold because of the inconsistent results that would result in notice requirements for urban and rural communities.[317] The Department also considered requiring translation of the Notice of Availability in the ''top 15'' languages to the extent that there are at least 200 LEP speakers for a particular language in the relevant state or states. This standard would require fewer language translations for states such as Montana (notices in only 11 languages) and Wyoming (notices in only 4 languages). However, we declined to institute this alternative so as to not include an arbitrary cut-off, such as 200 LEP speakers, into the proposed regulation, and instead provided covered entities alternatives to the requirement to provide a Notice of Availability. We seek comment on this approach.

Proposed § 92.11(c) requires the notice be provided on an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants, and upon request at any time. Similar to the notice of nondiscrimination requirement in proposed § 92.10, the Notice of Availability would also be required to be provided at a conspicuous location on the covered entity's health program or activity website, if it has one, and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice. This notice must also be accessible to individuals with disabilities who require auxiliary aids and services. These requirements would pose a relatively low-cost burden for covered entities and ensure information about language assistance services is provided in locations that are highly visible and visited by members of the public.

In response to concerns raised by stakeholders regarding the lack of specificity in the term ''significant publications or significant communications,'' rather than providing a general class of documents for which the notice must be provided (*e.g.,* ''significant documents''), we propose in paragraph (c)(5) to provide a list of specific electronic and written communications that must be accompanied by the Notice of Availability. After consideration, we believe this approach is more tailored to the needs of LEP individuals and individuals with disabilities when accessing important information regarding a range of health programs and activities and provides the level of specificity sought by covered entities.

We propose to require the Notice of Availability to accompany the following documents: (i) the notice of nondiscrimination required by proposed § 92.10 of this part; (ii) the notice of privacy practices required by the implementing regulations for the Health Insurance Portability and Accountability Act of 1996 [318] (HIPAA) at 45 CFR 164.520; (iii) application and intake forms; (iv) notices of denial or termination of eligibility, benefits, or services, including Explanations of Benefits (EOBs), and notices of appeal and grievance rights; (v) communications related to a person's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant; (vi) communications related to a public health emergency; (vii) consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together); (viii) discharge papers; (ix) complaint forms; and (x) patient and member handbooks.

We considered limiting the requirement to include the notice of availability of language assistance services and auxiliary aids in EOBs to only those EOBs that notify individuals of a cost-sharing responsibility. In other words, an EOB showing that services have been fully covered and that the patient has no further financial responsibility for the service (including co-payment, co-insurance, disallowed cost for which a provider may bill the patient, or other charge) would not constitute a notice of a denial or termination of benefits or services, and therefore would not be required to include the notice of availability. However, we determined that the burden of administering a process to assess which EOBs fall under the requirement and then include the notice only to those EOBs would be more burdensome than the alternative of including the notice in all EOBs. We invite comment as to whether this is the most appropriate approach, balancing the burden of providing notices of availability with all EOBs against the burdens associated with determining which EOBs must include the notice.

To further alleviate the potential burdens of subsection (d), we propose alternative, optional methods by which a covered entity may be deemed in compliance with proposed § 92.11(a). First, pursuant to proposed paragraph (d)(1), a covered entity shall be deemed in compliance with respect to an individual if the covered entity, on an annual basis: provides individuals, in their primary language and through any appropriate auxiliary aids and services, the option to opt out of receipt of the Notice of Availability; does not condition receipt of any aid or service on the decision to opt out; informs the individual of their right to receive the notice upon request in their primary language and through any appropriate auxiliary aids and services, and that opting out of receiving the notice is not a waiver of their right to receive language assistance services and any appropriate auxiliary aids and services as required by this part in their primary language and through any appropriate auxiliary aid or service; documents, on an annual basis, the individual's decision to opt out; and does not treat a non-response from an individual as a decision to opt out. Second, proposed paragraph (d)(2) provides that a covered entity shall be deemed in compliance with this section with respect to an individual if the covered entity documents the individual's primary language and any appropriate auxiliary aids and services and either provides all materials and communications in that individual's primary language and through any appropriate auxiliary aids and services, or provides the notice required by § 92.11(a) in that individual's primary language and through any appropriate auxiliary aids

[315] 7 U.S.C. 2020(e)(1)(B).

[316] 7 CFR 272.4(b)(2); *see also* 65 FR 70143–44 (Nov. 21, 2000) (discussing access to households with language access barriers).

[317] *See* 43 FR 47846, 47849 (Oct. 17, 1978) (''Although many commenters suggested adoption of a uniform percentage test, the Department rejected that concept because it could require bilingual service in sparsely populated areas where only two or three households are of a single language minority. Conversely, in densely populated low-income areas, hundreds of single-language areas and hundreds of single-language minority households could be an insufficient number to meet the percentage test required for bilingual services.'').

[318] Public Law 104–191, 100 Stat. 2548 (1996).

and services in all communications that are identified in § 92.11(c)(5).

In drafting these proposed provisions, the Department considered alternative approaches, such as requiring covered entities to provide the Notice of Availability at every interaction with a participant or beneficiary, or simply adopting the approach in the 2016 Rule. However, the unnecessary duplication of requiring covered entities to provide a Notice of Availability at every interaction with a beneficiary outweighs any potential benefit, and simply adopting the approach in the 2016 Rule would not address confusion regarding covered entities' legal obligations related to the term ''significant documents'' or concerns expressed about financial burden. We also considered an opt-in approach whereby covered entities would offer individuals an opportunity to opt in to receiving a copy of a covered entity's Notice of Availability. However, given the varying nature of Section 1557 covered entities, it would be difficult to specify when covered entities must offer individuals the opportunity to opt in to receiving its Notice of Availability. More importantly, we believe that the information contained in the proposed Notice of Availability is indispensable to the receipt of services free from discrimination. Accordingly, by providing an opt-out option, proposed § 92.11 attempts to balance the potential financial burden on covered entities of providing the Notice of Availability against the essential need for individuals to understand their rights and therefore would limit the burden without jeopardizing individual access to information.

The Department believes the approach in this proposed rule emphasizes the importance of notifying individuals of their civil rights and makes clear the requirements for notifying individuals about important civil rights requirements. The Department also believes the proposed rule addresses concerns raised by covered entities in response to the 2016 Rule requirements.

We seek comment on whether the Notice of Availability requirement as proposed is practical and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the content of the Notice of Availability and requirements on when and where covered entities must provide the notice. We also seek comment as to whether it adequately addresses the specific concerns raised regarding the burdens associated with the 2016 Rule requirements by providing a list of specific documents with which the Notice of Availability must be provided. Additionally, we seek comment on how to best provide the Notice of Availability to individuals with disabilities to ensure they know how to request and receive relevant materials and documents in formats that meet their disability-related needs, and whether covered entities should be required to provide the Notice of Availability in sign language. Similarly, we seek comment on how to best provide the Notice of Availability to LEP individuals, including LEP individuals with disabilities, to ensure they know how to request and receive language assistance services and auxiliary aids and services to provide meaningful access to relevant materials and documents. We also seek comment on whether the list of communications proposed adequately captures the documents for which LEP individuals and individuals with disabilities should receive the Notice of Availability. We further seek comment on the anticipated costs to covered entities of various sizes to comply with the proposed requirements.

Data Collection

Commenters on the 2015 NPRM requested that OCR require covered entities to collect additional data, beyond those required by the referenced statutes and their regulations, on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age, in part so that such entities could better plan how to meet the needs of those populations.[319] We considered including a provision in the rule requiring covered entities to collect additional civil rights data given the vital role data can play in ensuring civil rights compliance and the fact that such data remain largely uncollected for many demographic subgroups. At this time, however, we are not including such a provision but are soliciting feedback and comments on such data collection to inform a final rule and OCR's overall civil rights work.

The COVID–19 pandemic serves as an example of the importance of access to data collection in addressing harm at the earliest possible stages of a public health emergency in order to provide effective and lifesaving health care. In the early days of the COVID–19 pandemic, public health officials lacked the data necessary to gain a full picture of how the pandemic was impacting marginalized communities, prompting the publication of tools like the COVID Racial Data Tracker. The COVID Racial Data Tracker was created out of a collaboration between the COVID Tracking Project and the Boston University Center for Antiracist Research to gather racial and ethnic demographic data to understand the outbreak of COVID–19 and protect vulnerable communities.[320] Indeed, as the COVID–19 pandemic has highlighted, the lack of demographic data can make it challenging to determine where public health disparities are occurring and where to allocate resources such as COVID–19 testing and vaccinations.[321] These issues have civil rights implications. Just as nearly all of the provisions in this proposed rule benefit Section 1557 covered entities as much as they benefit the public, a data collection provision has the potential to benefit state and local health departments because they would be able to use the data they collect to reveal existing health disparities and proactively allocate and disseminate the resources necessary to address public health disparities.

Since the beginning of the COVID–19 pandemic, the Federal Government has responded with several data collection resources—which can be used by Federal, State, territorial, and local governments alike—to provide a clearer picture of how COVID–19 is impacting communities across the country. Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' established the Interagency Working Group on Equitable Data with the goal of collecting more disaggregated data across Federal agencies to be better equipped to measure and advance equity through the work of every Federal agency.[322] Data that the Federal Government has recently made available can continue to be used to reveal and address long-existing health disparities. Some examples of health data the Federal Government is collecting include those in HHS' Protect Public Data Hub,[323] which is a secure data ecosystem for sharing, parsing, housing, and accessing COVID–19 data; CDC data

[319] 81 FR 31375, 31392–93 (May 18, 2016).

[320] *About the Racial Data Tracker, covidtracking.com, https://covidtracking.com/race/about* (last visited June 15, 2022).

[321] *See* Tom Simonite, *Covid Hits Minorities Hardest, But Data Often Doesn't Show It,* Wired Business (Aug. 24, 2020, 7:00 a.m.), *https://www.wired.com/story/covid-hits-minorities-hardest-data-doesnt-show/*; Laura Barron-Lopez et al., *Missing Data Veils Coronavirus Damage to Minority Communities,* Politico (June 14, 2020, 7:00 a.m.), *https://www.politico.com/news/2020/06/14/missing-data-veils-coronavirus-damage-to-minority-communities-316198.*

[322] 86 FR 7009 (Jan. 25, 2021).

[323] *HHS Protect Public Data Hub, https://protect-public.hhs.gov/* (last June 15, 2022).

on COVID–19 cases and deaths by state or territory; [324] those in the *HealthData.gov* COVID–19 Reported Patient Impact and Hospital Capacity by State Timeseries, which provides state-aggregated data for hospital utilization in a timeseries format; [325] and those in the *HealthData.gov* COVID–19 Diagnostic Laboratory Testing Time Series, which reports COVID–19 test results from over 1,000 U.S. laboratories and testing locations, including commercial and reference laboratories, public health laboratories, and other testing locations.[326] This is not an exhaustive list of the Federal Government's data collection activities, but merely identifies some examples of what has changed since the beginning of the COVID–19 pandemic.

When considering adding a data collection provision to this proposed rule, the Department contemplated what kind of additional data we might require covered entities to collect and from which covered entities the Department should collect such data. In addition to race, ethnicity, language, age, and disability, we considered requiring covered entities to collect data on sex, gender, gender identity, and sexual orientation from patients and health care providers. Some states and territories, including California and Washington, DC, currently require plans sold on their Health Insurance Exchanges to collect demographic data about enrollees' race and ethnicity, but not sexual orientation or gender identity.[327] In Colorado, a new state law will require issuers to offer a standardized ''Colorado Option'' plan on the State Exchange in 2023, which includes a requirement to offer a culturally responsive network of providers.[328] Additionally, the state's law requires issuers to attempt to collect demographic data, including race, ethnicity, disability status, sex, sexual orientation, and gender identity from their providers and the providers' front office staff.[329] The Department understands there may be concerns related to requiring covered entities to collect deeply personal data. On one hand, the access to such data can provide a clearer picture of disparities and gaps in patient outcomes and representation in the provision of care. On the other hand, some providers and patients are hesitant to provide data on their race, sexual orientation, or gender identity for fear of discrimination.[330] The Department recognizes the challenges associated with requiring covered entities to collect such data.

The Department believes that rather than codifying a specific set of data collection measures within this rulemaking, the Department—through OCR—is better positioned to create a dynamic and responsive civil rights data collection structure by using its existing authorities. OCR does have the authority to request compliance data from covered entities under its existing civil rights authorities, which we propose to codify for purposes of Section 1557 at proposed § 92.303(a) (incorporating by reference 45 CFR 80.6 with regard to recipients and State Exchanges) and proposed § 92.303(c) (with regard to the Department and Federally-facilitated Exchanges). Using our existing authorities would be similar to the Department of Education (ED)'s civil rights data collection process. Since 1968, ED's Office for Civil Rights has, without a regulatory standard for a recurring civil rights data collection, required its elementary and secondary education recipients to collect data [331] on the leading civil rights data indicators related to access and barriers to an educational opportunity from early childhood through 12th grade, disaggregated by race/ethnicity, sex, disability, and English Learner status.[332] By using existing authorities, the Department believes OCR will have the flexibility to be responsive to the critical health-related civil rights issues that may arise in the future.

We seek comment on this general approach, including whether covered entities are already collecting disaggregated demographic data in their health programs and activities and, if so, for which categories of data, through what systems, and at what cost. We also seek comment on how a civil rights data collection requirement could impact current data collection efforts, either positively or negatively. We also seek comment on whether the adoption of a regulatory standard for a recurring civil rights data collection would benefit civil rights enforcement, as well as how frequently the data should be submitted to OCR. We also seek comment on whether the data collection requirements should vary by type of entity, as recipients of Federal financial assistance include a variety of entities, including state and local agencies, health insurance issuers, health care providers, health care facilities and clinics, hospitals, federally qualified health centers, and health-related educational and training programs. Accordingly, we seek comment on which types of recipients (if any) should be covered; if recipients under a certain size should be exempt from the data collection requirement, and if so, should that be based on employee number, the number of beds (if relevant), or some other metric; what types of data should be collected; what definitions should be used; the potential costs associated with such a requirement; and the potential benefits of such a requirement.

Subpart B—Nondiscrimination Provisions

For the reasons described below, Subpart B of the proposed rule generally adopts certain regulatory provisions regarding specific discriminatory actions prohibited by the implementing civil rights statutes referenced in Section 1557(a): Title VI, Section 504, Title IX, and the Age Act.

Discrimination Prohibited (§ 92.101)

Proposed § 92.101(a) provides a general prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which Section 1557 or this part applies and provides additional detail regarding what constitutes discrimination on the basis of sex. Proposed paragraph (b) identifies some specific forms of prohibited discrimination.

Proposed paragraph (a)(1) provides the general prohibitions on discrimination under Section 1557 by restating the core objective of Section 1557: ensuring that covered entities do not discriminate on the basis of race, color, national origin, sex, age, or disability against any individual seeking

[324] *United States COVID–19 Cases and Deaths by State over Time, data.cdc.gov, https://data.cdc.gov/Case-Surveillance/United-States-COVID-19-Cases-and-Deaths-by-State-o/9mfq-cb36* (last updated June 15, 2022).

[325] *COVID–19 Reported Patient Impact and Hospital Capacity by State Timeseries, HealthData.gov, https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh* (last updated June 15, 2022).

[326] *COVID–19 Diagnostic Laboratory Testing (PCR Testing) Time Series, HealthData.gov, https://healthdata.gov/dataset/COVID-19-Diagnostic-Laboratory-Testing-PCR-Testing/j8mb-icvb* (last updated June 15, 2022).

[327] Markian Hawryluk, *Some Physicians Are Uneasy as Colorado Collects Providers' Diversity Data,* npr.org (April 25, 2022, 5:00 a.m.), *https://www.npr.org/sections/health-shots/2022/04/25/1094354537/colorado-doctor-diversity-data.*

[328] *Id.*

[329] *Id.*

[330] *Id.*

[331] ED's current authority to collect data comes from section 203(c)(1) of the Department of Education Organization Act (20 U.S.C. 3413(c)(1)) and is informed by the regulations implementing several of the civil rights statutes that it implements authorizing collection of data that are necessary to ensure compliance with civil rights laws within the jurisdiction of ED's OCR.

[332] 20 U.S.C. 3413(c)(1). *See also* 34 CFR 100.6(b), § 104.61, § 106.71; *Civil Rights Data Collection: Frequently Asked Questions,* U.S. Dep't of Educ., Office for Civil Rights, *https://www2.ed.gov/about/offices/list/ocr/frontpage/faq/crdc.html* (last modified Apr. 14, 2021).

to participate in or receive the benefits of the covered entity's health program or activity. Consistent with Federal case law [333] and existing Federal civil rights enforcement,[334] the Department's proposed nondiscrimination protections prohibit discrimination based upon a person's actual or perceived race, color, national origin, sex, age, or disability.

Proposed paragraph (a)(2) clarifies that discrimination on the basis of sex includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.

The proposed inclusion of ''sex stereotypes'' codifies the Supreme Court's holding in *Price Waterhouse* v. *Hopkins* that discrimination on the basis of sex stereotypes is a form of sex discrimination.[335] As the Court there explained, ''we are beyond the day when an employer could evaluate employees by assuming or insisting that they matched the stereotype associated with their group,'' for ''[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.'' [336] The Supreme Court reiterated this principle in *Bostock,* explaining that ''an employer who fires both [a woman] and [a man] for failing to fulfill traditional sex stereotypes doubles rather than eliminates Title VII liability.'' [337]

We are proposing to include ''sex characteristics'' because discrimination based on anatomical or physiological sex characteristics (such as genitals, gonads, chromosomes, hormone function, and brain development/anatomy) is inherently sex-based. Discrimination on the basis of intersex traits is similarly prohibited sex discrimination because the individual is being discriminated against based on their sex characteristics. If their sex characteristics were different—*i.e.,* traditionally ''male'' or ''female''—the intersex person would be treated differently. Moreover, like gender identity and sexual orientation, intersex traits are ''inextricably bound up with'' sex,[338] and ''cannot be stated without referencing sex.'' [339] The DOJ has similarly concluded that *Bostock*'s reasoning applies to discrimination based upon intersex traits.[340]

The proposed inclusion of ''pregnancy or related conditions'' is consistent with the longstanding interpretation of sex discrimination under Title IX, including the Department's Title IX implementing regulation.[341]

The proposed inclusion of ''sexual orientation'' and ''gender identity'' is consistent with the Supreme Court's reasoning in *Bostock.* As explained in the Department's Bostock Notification, the Court's reasoning applies to Title IX and, by extension, to Section 1557.[342] Given the similarity in nondiscrimination language between Title VII and Title IX, most Federal courts [343] that have addressed the issue, and the Departments of Justice and Education, have interpreted Title IX consistent with *Bostock's* reasoning.[344]

The *Franciscan Alliance* court concluded that the 2016 Rule's definition of ''sex'' as including ''gender identity'' was contrary to Section 1557 because ''Title IX and Congress' incorporation of it in [Section 1557 of] the ACA unambiguously adopted the binary definition of sex.'' [345] The Department disagrees. In *Bostock,* the Supreme Court held that the prohibition on discrimination ''because of . . . sex'' under Title VII covers discrimination on the basis of gender identity and sexual orientation even *assuming* that ''sex'' refers ''only to biological distinctions between male and female.'' [346] Title IX and Section 1557 prohibit discrimination ''on the basis of sex.'' [347] Because their statutory prohibitions against sex discrimination are similar, the Supreme Court and other Federal courts consistently look to interpretations of Title VII to inform Title IX.[348] Thus, *Bostock's* discussion of the text of Title VII informs the Department's analysis of Title IX and Section 1557.

First, like Title VII, Title IX and Section 1557 apply to sex discrimination against an individual. Title VII states that it is unlawful for an

[333] *See Fogleman* v. *Mercy Hosp.,* 283 F.3d 561, 572 (3d Cir. 2002) (employee of hospital employer may pursue retaliation claim even if employer's perception that employee was Muslim is factually incorrect); *EEOC* v. *WC&M Enters.,* 496 F.3d 393, 400–01 (5th Cir. 2007) (national origin harassment of an Indian Muslim employee included harassment based on the employer's perception that he was an Arab Muslim); *Glenn* v. *Brumby,* 663 F.3d 1312, 1319 (11th Cir. 2011) (''An individual cannot be punished because of his or her *perceived* gender-nonconformity.'') (emphasis added); *Jones* v. *UPS Ground Freight,* 683 F.3d 1283 (11th Cir. 2012) (employer may still be liable for harasser's use of epithets associated with an ethnic or racial minority different than that of the plaintiff employee); *Estate of Lance* v. *Lewisville Indep. Sch. Dist.,* 743 F.3d 982, 991 (5th Cir. 2014) (''. . . [section] 504's reach extends not only to individuals who in fact have a disability, but also to individuals who are regarded as having a disability (whether or not that perception is correct)''); *but cf. El* v. *Max Daetwyler Corp.,* 451 F. App'x 257 (4th Cir. 2011) (per curiam opinion affirmed district court's order granting employer's motion to dismiss because Title VII does not ''contain an explicit provision for the protection of persons who are merely perceived to be a part of a protected class'').

[334] *See* U.S. Equal Emp't Opportunity Comm'n, *EEOC Enforcement Guidance on National Origin Discrimination,* n.16 (Nov. 18, 2016), *https://www.eeoc.gov/laws/guidance/national-origin-guidance.cfm#ftn16* (Title VII prohibits employer actions that have the purpose or effect of discriminating against persons because of their real or *perceived* race, national origin, or association with a particular religion) (emphasis added); *Housing Discrimination and Persons Identified as Lesbian, Gay, Bisexual, Transgender, and/or Queer/Questioning (LGBTQ),* U.S. Dep't of Hous. & Urban Dev., *https://www.hud.gov/program_offices/fair_housing_equal_opp/housing_discrimination_and_persons_identifying_lgbtq* (last updated Feb. 1, 2022) (''Persons who identify as LGBTQ and believe they have experienced housing discrimination because of their actual or *perceived* sexual orientation or gender identity can assert their rights under the Fair Housing Act by filing a complaint with HUD.'') (emphasis added); *Race and National Origin Discrimination Frequently Asked Questions,* U.S. Dep't of Educ., *https://www2.ed.gov/about/offices/list/ocr/frontpage/faq/race-origin.html* (last modified Jan. 1, 2020) (''Discrimination on the basis of race, color, national origin includes discrimination based on a person's actual or *perceived* race, color, national origin, ethnicity, or ancestry.'') (emphasis added).

[335] 490 U.S. 228, 250–51 (1989).

[336] *Id.; cf. U.S.* v. *Virginia,* 518 U.S. 515, 533 (1996) (in making classifications based on sex, states ''must not rely on overboard generalizations about the different talents, capacities, or preferences of males and females'').

[337] *Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731, 1742–43 (2020).

[338] *Id.* at 1742.

[339] *Grimm* v. *Gloucester Cty. Sch. Bd.,* 972 F.3d 586, 608 (4th Cir. 2020) (quoting *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034, 1051 (7th Cir. 2017)).

[340] *See* Memorandum from Kristen Clarke, Assistant Att'y Gen., Civil Rights Div., U.S. Dep't of Justice, to Dep't of Justice Office of Justice Programs, Office of Cmty. Oriented Policing Servs., Office on Violence Against Women, & Money Laundering & Asset Recovery Section, 2 (Mar. 10, 2022), *https://www.justice.gov/crt/page/file/1481776/download;* U.S. Dep't of Justice, Title IX Legal Manual, Title IX Cover Addendum post-Bostock (updated Aug. 12, 2021), *https://www.justice.gov/crt/title-ix#Bostock.*

[341] *See Conley* v. *Northwest Fla. State Coll.,* 145 F. Supp. 3d 1073 (N.D. Fla. 2015). *See also* 45 CFR 86.21(c)(2), (3); § 86.40(b)(1), (4), (5); § 86.51(b)(6); § 86.57(b)(d) (Title IX regulation).

[342] 86 FR 27984 (May 25, 2021).

[343] *Doe* v. *Snyder,* No. 21–15668, 2022 WL 711420, at *9 (9th Cir. Mar. 10, 2022); *Grimm* v. *Gloucester Cty. Sch. Bd.,* 972 F.3d at 616; *Koenke* v. *Saint Joseph's Univ.,* No. 19–cv–4731, 2021 WL 75778, at *2 (E.D. Pa. Jan. 8, 2021); *Doe* v. *Univ. of Scranton,* No. 3:19–cv–01486, 2020 WL 5993766, at *11 n.61 (M.D. Pa. Oct. 9, 2020); *but see Neese* v. *Becerra,* No. 2:21–cv–00163–Z, 2022 WL 1265925, at *14 (N.D. Tex. Apr. 26, 2022) (denying motion to dismiss, finding ''at this stage of litigation, the approved tools of textualism do not support'' application of *Bostock* to ''Title IX—and by extension Section 1557'').

[344] Karlan Memo, *supra* note 46; *86 FR 32637 (June 22, 2021) (Department of Education).*

[345] *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 689 (N.D. Tex. 2016).

[346] 140 S. Ct. at 1744.

[347] 20 U.S.C. 1681(a); 42 U.S.C. 18116.

[348] *See, e.g., Franklin* v. *Gwinnett Cty. Pub. Sch.,* 503 U.S. 60, 75 (1992); *Jennings* v. *Univ. of N.C.,* 482 F.3d 686, 695 (4th Cir. 2007); *Gossett* v. *Oklahoma ex rel. Bd. of Regents for Langston Univ.,* 245 F.3d 1172, 1176 (10th Cir. 2001).

employer ''to fail or refuse to hire or to discharge any *individual,* or otherwise to discriminate against any *individual*'' regarding their ''compensation, terms, conditions, or privileges of employment, because of such *individual's* race, color, religion, sex, or national origin.'' [349] The *Bostock* Court focused on this feature of Title VII in reaching its holding.[350] Similarly, Title IX states that ''no *person* in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.'' [351] Furthermore, Section 1557 provides that ''an *individual* shall not, on the ground prohibited [under Title VI, Title IX, the Age Act, or Section 504] 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.'' [352]

Second, Title IX's ''on the basis of'' sex language is sufficiently similar to ''because of'' sex under Title VII as to be considered interchangeable. In *Bostock* itself, the Supreme Court described Title VII's language that way: ''[I]n Title VII, Congress outlawed discrimination in the workplace on the basis of race, color, religion, sex, or national origin.'' [353] The *Bostock* Court concluded that Title VII's prohibition of discrimination ''because of'' sex includes discrimination because of sexual orientation and transgender status, finding that when an employer discriminates against employees for being gay or transgender, ''the employer must intentionally discriminate against individual men and women in part because of sex.'' [354] Indeed, the Court clearly held that it is ''impossible to discriminate against a person'' for being gay or transgender ''without discriminating against that individual on the basis of sex.'' [355]

The same reasoning in *Bostock* supports the interpretation that Title IX's prohibition of discrimination ''on the basis of'' sex, and, relatedly, that Section 1557's prohibition on discrimination ''on the ground prohibited under Title IX'' prohibits covered entities from discriminating against an individual based on that person's sexual orientation or transgender status. After considering the text of Title IX and Section 1557, Supreme Court case law, and developing jurisprudence in this area, the Department has determined that the best reading of Title IX's prohibition on discrimination ''on the basis of sex'' and Section 1557's prohibition on discrimination ''on the ground prohibited under Title IX'' is that it includes discrimination on the basis of gender identity and sexual orientation. Should there be any ambiguity read into the statutory text of Title IX or Section 1557 with regard to this issue, the Department would nonetheless adopt this interpretation given the statutory objectives of the civil rights statutes and the importance of ensuring that individuals are able to receive health care free from discrimination.

Proposed paragraph (b) identifies several specific forms of prohibited discrimination under Section 1557. It does so by incorporating by reference the specific prohibitions on discrimination in the regulations implementing each civil rights statute referenced in Section 1557's statutory text. Even though Section 1557 provides an independent basis for the regulation of discrimination in covered programs and activities, this proposed section expressly adopts the specific prohibitions on discrimination found in the implementing regulations of the referenced antidiscrimination statutes. We believe this approach is appropriate in light of Section 1557's express adoption of the same language used in the four referenced statutes to describe the nature of the prohibited conduct—namely, causing an individual to ''be excluded from participation in, be denied the benefits of, or be subjected to discrimination under'' a specified program or activity. Incorporating by reference the regulations that have long described certain forms of such conduct under those specified statutes is consistent with the ACA and provides clarity, while not including redundant text in this rule. The text proposes to direct the reader to the ''prohibitions on discrimination'' in sections of the Title VI, Section 504, Title IX (subparts C and D), and Age Act (subpart B) regulations. This is similar to the approach taken in the 2016 Rule but, rather than citing specific provisions, we propose a general reference.

Though the 2020 Rule purported to clarify covered entities' Section 1557 obligations, it sought to do so through general statements. The 2020 Rule, at § 92.2, generally provides the nondiscrimination requirements of Section 1557 by restating the statutory language of 42 U.S.C. 18116(a), followed by stating that the grounds prohibited are the grounds found in the Title VI, Title IX, Section 504, and Age Act statutes. This approach has caused confusion by eliminating guidance as to certain specific discriminatory actions that one generally finds in an implementing regulation for a civil rights statute. The Department believes it is helpful for covered entities and protected individuals to have additional clarity regarding some common, specific prohibitions under Section 1557.

We believe the proposed approach is the most reasonable reading of Section 1557's direction that ''an individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).'' [356] Because this language is adapted from the four referenced statutes, it is reasonable and appropriate to look to those statutes' implementing regulations to further clarify what it means to discriminate on the grounds prohibited by those statutes. Rather than restating each of the specific prohibitions on discrimination under each implementing regulation, we propose that § 92.101(b) simply cross-reference the implementing regulations of these referenced civil rights statutes. Note that this proposed rule does not in any way limit or impact the interpretation of those statutes.

Proposed paragraph (b)(1)(i) specifically refers to recipients of Federal financial assistance and State Exchanges; proposed paragraph (b)(1)(ii) refers to the Department's health programs and activities, including Federally-facilitated Exchanges. Under both of these paragraphs, covered entities would be prohibited from the discriminatory actions found in the applicable sections of the Title VI, Title IX, and Age Act implementing regulations, found at 45 CFR parts 80, 86 (subparts C and D), and 91 (subpart B), respectively. For the specific discriminatory actions provided for in Section 504 implementing regulation, recipients and State Exchanges will look

[349] 42 U.S.C. 2000e–2(a)(1) (emphasis added).

[350] *Bostock,* 140 S. Ct. at 1740–41 (''[The statute] tells us three times—including immediately after the words ''discriminate against''—that our focus should be on individuals.'').

[351] 20 U.S.C. 1681(a) (emphasis added).

[352] 42 U.S.C. 18116 (emphasis added).

[353] *Bostock,* 140 S. Ct. at 1737; *see also Meritor Sav. Bank, FSB* v. *Vinson,* 477 U.S. 57, 64 (1986) (''[W]hen a supervisor sexually harasses a subordinate because of the subordinate's sex, that supervisor 'discriminate[s]' on the basis of sex.'') (emphasis added).

[354] *Bostock,* 140 S. Ct. at 1740–43.

[355] *Id.* at 1741.

[356] 42 U.S.C. 18116(a).

to the implementing regulation at 45 CFR part 84 (federally funded), and the Department will look to the implementing regulation at 45 CFR part 85 (federally conducted).

Proposed paragraph (b)(2) provides that the enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general application of the prohibition in proposed paragraph (a) of this section. Although some of these provisions would articulate specific forms of prohibited discrimination that have not otherwise been articulated under some of the underlying statutes referenced in Section 1557, these provisions are included to ensure parity across all prohibited bases of discrimination under Section 1557 with regard to covered entities' health programs and activities.

The 2016 Rule included, at former § 92.101(b)(3)(ii) and (iii), provisions specifically related to prohibited discrimination on the basis of sex related to criteria and methods of administration and selection of facility sites and locations that have the effect of discriminating on the basis of sex or the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex. The 2020 Rule removed these paragraphs. The 2016 Rule language is similar to language found in the implementing regulations for Title VI, Section 504, and the Age Act.[357] The Department has determined not to include a similar provision here as the Department believes it is important to preserve—and not expand—the longstanding treatment of disparate impact in the referenced statutes' implementing regulations. We seek comment on this approach, including whether a provision similar to that included in the 2016 Rule is necessary, and whether it should be limited to discrimination on the basis of sex, or should also include each of the enumerated grounds covered under Section 1557's statutory prohibition on discrimination.

Subpart C—Specific Applications to Health Programs and Activities

Because of Section 1557's unique application to health programs and activities, Subpart C provides additional specificity regarding nondiscrimination requirements in this setting. The provisions in this subpart are responsive to the nature and importance of health care, health insurance, and related decision-making as it impacts individuals and communities protected by Section 1557's prohibition of discrimination. These provisions are intended to provide clear instruction to covered entities and are informed by OCR's stakeholder outreach and experience in both enforcement and in providing technical assistance.

Meaningful Access for Limited English Proficient Individuals (§ 92.201)

Proposed § 92.201 effectuates Section 1557's prohibition on national origin discrimination as it is applied to LEP individuals in covered health programs and activities. For LEP individuals, the lack of proficiency in English and the use of non-English languages is often tied to their national origin. It is well-established that an entity may violate Title VI and its implementing regulation by failing to take reasonable steps to provide meaningful access to LEP individuals.[358] The provision of free and effective language assistance services to LEP individuals is essential to ensure compliance with nondiscrimination laws.

Proposed paragraph (a) provides that covered entities ''must take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be directly affected by its health programs and activities.'' This language is nearly identical to the 2016 Rule at former § 92.201(a), which required a covered entity to take reasonable steps to provide meaningful access to each LEP individual ''eligible to be served or likely to be encountered.'' [359] The Department is proposing to revise this language slightly to include individuals likely to be ''directly affected'' rather than ''encountered.'' This language is consistent with the 2003 HHS LEP Guidance [360] and OCR resolution agreements,[361] and we believe this language provides more clarity for covered entities regarding the individuals for whom reasonable steps must be taken. As the Department has advised in the past, ordinarily, persons eligible to be served or likely to be directly affected by a recipient's program are those persons who are in the covered entity's service area, and who either are eligible for the covered entity's benefits or services, or otherwise might be directly affected by such an entity's conduct. For example, a parent seeking health services for a child would be seen as directly affected by a covered entity's policies and practices.[362]

The language of the 2020 Rule differs from the 2016 Rule in that it requires reasonable steps to ensure meaningful access ''to programs or activities by limited English proficient individuals,'' rather than ''each'' LEP individual.[363] The preamble to the 2020 Rule explains this change by arguing that the 2016 Rule's ''stringent requirement . . . could potentially be interpreted to require a covered entity to provide language assistance services to every LEP individual it comes into contact with.'' [364] The plain language of the 2016 Rule in fact required that covered entities must take *reasonable steps* to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities.[365] For example, a surgeon would likely determine that it is a reasonable step to provide an interpreter when discussing the risks and aftercare of a particular procedure with an LEP individual in order to afford that individual meaningful access; however, a hospital may determine that reasonable access can be provided via sight translation of a generic brochure for an LEP patient rather than providing a fully translated version. This standard does not impose a significant burden on covered entities, as it does not mandate that every LEP individual receive language services,

[357] 45 CFR 80.3(b)(2), (3) (Title VI); § 84.4(b)(4), (5) (Section 504); § 90.12.(b) (Age Act).

[358] *See, e.g., Lau* v. *Nichols,* 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students of Chinese origin with limited English proficiency to take affirmative steps to provide the students with a meaningful opportunity to participate in federally funded educational programs); Dep't of Health, Educ., & Welfare, Identification of Discrimination and Denial of Services on the Basis of National Origin, 35 FR 11595 (July 18, 1970); E.O. 13166, Improving Access to Services. for Persons with Limited English Proficiency, 65 FR 50121 (Aug. 16, 2000) (directing Federal agencies that extend assistance subject to the requirements of Title VI to publish guidance for their respective recipients clarifying the obligation to provide language services to LEP individuals); Dep't of Justice, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 67 FR 41455, 41457 (June 18, 2002); Dep't of Educ., Office for Civil Rights & Dep't of Justice, Civil Rights Div., Dear Colleague Letter: English Learner Students and Limited English Proficient Parents (Jan. 7, 2015), *https://www2.ed.gov/about/offices/list/ocr/letters/colleague-el-201501.pdf.*

[359] Former 45 CFR 92.201(a).

[360] 68 FR 47311, 47314 (Aug. 8, 2003).

[361] *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't Health & Human Servs., Office for Civil Rights & Pa. Dep't of Human Servs. (2019), *https://www.hhs.gov/sites/default/files/hhs-padhs-vra.pdf.*

[362] *See, e.g.,* 65 FR 52762, 51767–68 (Aug. 30, 2000).

[363] 85 FR 37160, 37245 (June 19, 2020); 45 CFR 92.101(a).

[364] 85 FR 37210.

[365] 81 FR 31375, 31470 (May 18, 2016).

but rather that covered entities at a minimum conduct a reasonable steps evaluation for each LEP individual. However, the Department notes that, as the availability of telephonic interpreters increases, the evaluation of the reasonableness of providing language services shifts.

Taking reasonable steps to assess and meet the needs of each LEP individual eligible to be served or likely to be directly affected by the covered entity's health program or activity is important to ensure compliance with both Title VI and Section 1557. The need for a case-by-case determination is particularly important in the area of health care. As noted in the preamble to the 2016 Rule,

> [S]afe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes. This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death. Indeed, the provision of health care services, by its 'very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust,' which cannot be established without effective communication.[366]

Ensuring accurate, timely, and high-quality communication within the health care context is particularly important to LEP individuals and their families, who can be put in danger by not understanding a physician or other health care provider and the health protocols those individuals may prescribe. For example, an LEP parent or guardian may leave a doctor's office misunderstanding how to properly care for their child, putting the well-being of the child at risk due to miscommunication between the parent or guardian and the doctor regarding the health details of the child. Vigorous communication standards are extremely important in helping to minimize the health care risks LEP people face in the health care system, including lower rates of outpatient follow up, poor medication adherence, and a lack of understanding of diagnosis and discharge instructions.[367] Nothing has changed in this regard since the publication of the 2016 Rule; rather, the COVID–19 pandemic has demonstrated how critical meaningful access to health programs and activities is for the health and well-being of LEP individuals. A recent study documented the unique challenges faced by LEP individuals during the COVID–19 pandemic. The authors explained that factors like under-interpretation of complex conversations, non-universal use of interpreters, fewer conversations throughout the day with staff, not receiving important medical paperwork in their native language, and being separated from social support networks that often assist with the navigation of health care systems exacerbated these challenges for LEP individuals under the social isolation of inpatient care settings during the strict COVID–19 no visitation policies.[368]

Proposed paragraph (b) states that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of an LEP individual. This provision is similar to those included in the 2016 Rule at former § 92.201(c) and the 2020 Rule at § 92.101(b)(2) and is consistent with longstanding Title VI requirements and the HHS LEP Guidance.[369] The Department reminds states that they have the option to claim Medicaid reimbursement for the cost of interpretation services, either as medical-assistance or administration related expenditures.[370]

Proposed paragraph (c) provides specific requirements for interpreter and translation services. Proposed paragraph (c)(1) states that when interpreter services are required under this part, a covered entity must offer a qualified interpreter. Proposed paragraph (c)(2) provides that when translation services are required under this part, a covered entity must use a qualified translator. These terms are defined in the definitions section at proposed § 92.4.

Proposed paragraph (c)(3) addresses the use of machine translation by covered entities. Machine translation, which can involve speech-based machine translation to facilitate patient-provider communication as well as text-based machine translation to develop multilingual health materials, is increasingly being used as a method to assist communication in the health care setting and increase access to in-language health resources.[371] While the technology behind machine translation has improved in accuracy, the possibilities of significant consequences from inaccurate translation continue to exist.[372] During the COVID–19 pandemic, several states and some territories received complaints from LEP individuals because they were unable to sign up for COVID–19 vaccines on websites using machine translation or found translated information confusing because of inaccuracies in some translations.[373] The prevalence of inaccuracies was highlighted in a recent literature review of articles discussing machine translation in the health care context, which found that no matter the language or form of machine translation, all studies indicated error rates so high as to be ''unacceptable for actual deployment in health settings.'' [374]

The Department proposes regulatory language requiring a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an LEP

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[366] *Id.* at 31413.

[367] U.S. Dep't Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Guide to Preventing Readmissions Among Racially and Ethnically Diverse Medicare Beneficiaries, p. 4 (Sept. 2015), *https://essentialhospitals.org/wp-content/uploads/2016/01/OMH_Readmissions_Guide.pdf.*

[368] Natale K. Kucirek et al., *Stories from COVID–19 Reveal Hospitalized Patients with Limited English Proficiency Have Always Been Uniquely Prone to Social Isolation,* 36 J. of General Internal Med. 786, 789 (2021), *https://doi.org/10.1007/s11606-020-06383-z.*

[369] 68 FR 47316.

[370] *See Translation and Interpretation Services,* Ctrs. for Medicare & Medicaid Servs., *https://www.medicaid.gov/medicaid/financial-management/medicaid-administrative-claiming/translation-and-interpretation-services/index.html* (last visited June 15, 2022).

[371] Kristin N. Dew et al., *Development of Machine Translation Technology for Assisting Health Communication: A Systematic Review,* 85 J. of Biomedical Informatics 56, 57 (2018), *https://reader.elsevier.com/reader/sd/pii/S1532046418301448?token=D92E78CBB86826ADC4834 79DED4B8E8442AE7763 0BCCB53F5385AE5AD2452E 7FFC803B8CBA43AC533 A509E3F977291BC&originRegion=us-east-1&originCreation=20220615184038.*

[372] *See* Wenxiu Xie et al., *Predicting Risks of Machine Translations of Public Health Resources by Developing Interpretable Machine Learning Classifiers,* 18 Int. J. Environ. Res. Pub. Health 8789 (2021), *https://www.mdpi.com/1660-4601/18/16/8789/htm*; Lucas N. Vieira et al., *Understanding the Societal Impacts of Machine Translation: A Critical Review of the Literature on Medical and Legal Use Cases,* 24 Info., Comm., & Soc'y 1515 (2020), *https://www.tandfonline.com/doi/full/10.1080/1369118X.2020.1776370;* Nicole Wetsman, *Google Translate Still Isn't Good Enough for Medical Instructions,* The Verge (Mar. 9, 2021), *https://www.theverge.com/2021/3/9/22319225/google-translate-medical-instructions-unreliable;* Breena R. Taira et al., *A Pragmatic Assessment of Google Translate for Emergency Department Instructions,* 36 J. Gen. Intern. Med. 3361 (2021), *https://link.springer.com/article/10.1007%2Fs11606-021-06666-z;* Mark P. Sendak et al., *A Path for Translation of Machine Learning Products into Healthcare Delivery,* EMJ Innov., Jan. 27, 2021, *https://emj.emg-health.com/wp-content/uploads/sites/2/2020/01/A-Path-for-Translation-of-Machine-Learning.....pdf;* Dew, *supra* note 371.

[373] Julie Zauzmer Weil, *DC Says Long-Awaited Translation of Vaccine Website Is Coming This Weekend,* Wash. Post (Apr. 9, 2021), *https://www.washingtonpost.com/local/coronavirus-vaccine-translation-spanish/2021/04/09/40ed126a-9942-11eb-962b-78c1d8228819_story.html.*

[374] Dew, *supra* note 371, at 64.

individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language.

We seek comment on the use of machine translation in health programs and activities generally, other possible approaches to address this issue, and whether there should be an exception to this provision to allow for the limited use of machine translation in exigent circumstances.

Proposed paragraph (d) addresses how the Director will evaluate compliance with this section. The 2015 NPRM in then-proposed § 92.201(b)(1) provided that the Director would evaluate a covered entity's compliance with meaningful access for LEP individuals by giving substantial weight to the nature and importance of the program or activity and the particular communication at issue.[375] The 2015 NPRM also identified five other relevant factors that the Director would consider.[376] In response to comments, the preamble to the 2016 Rule eliminated the list of five factors and articulated only one factor in former § 92.201(b)(2): whether a covered entity had developed and implemented an effective written language access plan appropriate to its circumstances.[377] Commenters suggested many other factors that could be included.[378] The preamble explained that including multiple illustrative factors in the regulatory text may create the erroneous impression that the Director will not consider other relevant factors, and trying to capture all possible factors could result in an unintentionally unworkable regulatory scheme.[379] Accordingly, the preamble to the 2016 Rule contains a lengthy list of factors that may be relevant in a particular case, including:

> the length, complexity, and context of the communication; the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity; the frequency with which a covered entity encounters the language in which the individual communicates; whether a covered entity has explored the individual's preference, if any, for a type of language assistance service, as not all types of language assistance services may work as well as others in providing an individual meaningful access to the covered entity's health program or activity; the cost of language assistance services and whether a covered entity has availed itself of cost-saving opportunities; and all resources available to the covered entity, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained.[380]

At paragraph (d)(1), we propose that the Director shall evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the LEP individual. This is the same language as was included in the 2016 Rule.[381] Proposed paragraph (d)(2) provides that the Director shall take into account other relevant factors, including the effectiveness of the covered entity's written language access procedures for its health programs and activities, that the covered entity has implemented pursuant to proposed § 92.8(d) of this part. In this proposed regulation, we are not requiring a formal language access plan; however, we continue to strongly encourage covered entities to develop such plans, in concert with developing and implementing language access procedures required under proposed § 92.8(d), to be in a better position to meet their obligations to provide effective language services in a timely manner.

The proposed language contrasts with the 2020 Rule which, at § 92.101(b)(1), provides that the Director will assess how the covered entity balances four factors,[382] essentially adopting the ''four-factor analysis'' found in the HHS LEP Guidance.[383] The preamble to the 2020 Rule notes that ''some commenters believed that 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 weakens recipient language access obligations to serve persons who speak infrequently encountered languages.'' [384] The 2020 Rule preamble states that OCR viewed the four-factor analysis as an appropriate way ''to allow flexibility for covered entities.'' [385]

During the four years that these provisions of the 2016 Rule were in effect, former § 92.201(a) was never challenged. However, the standard contained in the 2020 Rule has been challenged in Federal district court. In *Chinatown Service Center,* plaintiffs alleged that the 2020 Rule's replacement of the standard in former § 92.201(a) resulted in only a ''generalized duty'' to LEP individuals rather than a case-by-case review to ensure the covered entities take reasonable steps to provide each individual with limited English proficiency with necessary language assistance services.[386]

After reviewing and reconsidering comments received in response to the 2019 NPRM, we believe that the four-factor analysis is more appropriately described as a general framework for planning on a system-wide and site-level basis, but does not provide clarity as to what the covered entity's obligations are to a particular individual. The proposed rule applies the general obligation to take reasonable steps to provide meaningful access and focuses on the steps the covered entity must take for each individual in the health care setting.

The level of specificity we propose is especially important when addressing benefits or services with high importance or consequences such as those provided in the health care setting. This specificity helps guide a covered entity by supplying a framework that they can choose to use, while providing a covered entity an appropriate level of flexibility to determine how best to comply with statutory and regulatory obligations to provide meaningful access to LEP individuals. Therefore, while we have taken the four-factor analysis into consideration in formulating the specific provisions, we decline to include it in this proposed regulation. We seek comment on this approach.

Proposed paragraph (e) identifies restrictions on the use of certain persons to provide language assistance services for LEP individuals. This language is similar to that contained in the 2020 Rule at § 92.101(b)(4), with additional descriptors to ensure the best available and most accurate language assistance services in covered health programs and activities.[387] Proposed paragraph (e)(1) prohibits covered entities from requiring LEP individuals to provide, or pay for,

[375] 80 FR 54171, 54218 (Sept. 8, 2015).

[376] *Id.*

[377] 81 FR 31470.

[378] *Id.* at 31415.

[379] *Id.*

[380] *Id.* at 31416.

[381] Former 45 CFR 92.201(b)(1).

[382] *See* 85 FR 37245.

[383] 68 FR 47311, 47314 (Aug. 8, 2003) (suggesting, as a starting point for covered entities meeting their obligations, the balancing of four factors: (1) the number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs).

[384] 85 FR 37212.

[385] *Id.*

[386] *See Chinatown Serv. Ctr.* Compl., *supra* note 309.

[387] 85 FR 37246.

their own interpreters. Proposed paragraph (e)(2) provides for very limited situations in which an adult, not qualified as an interpreter, accompanying an LEP individual can serve as an interpreter. The first limited circumstance includes 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 LEP individual immediately available. For example, directly following a natural disaster such as an earthquake, a covered entity may temporarily rely on a non-qualified interpreter to help first responders provide services to LEP individuals during emergency response and recovery efforts. This is permitted only as a temporary measure while finding a qualified interpreter, and the qualified interpreter that arrives must confirm or supplement the initial communications with the accompanying adult.

In the second limited circumstance, an adult who is not qualified as an interpreter may also serve as an interpreter when: an LEP individual specifically requests that the accompanying adult interpret or facilitate communication; the accompanying adult agrees to provide such assistance; the request and agreement by the accompanying adult is documented; and reliance on that adult for such assistance is appropriate under the circumstances. When considering whether the reliance on such an adult to interpret without confirming or supplementing the interpretation is appropriate, the covered entity should consider the accompanying adult's language proficiency in both English and the primary language of the LEP individual; the possibility of bias; whether the individual is an interested party, such as in situations of domestic violence; and whether the accompanying adult helps the covered entity better understand the LEP individual. Covered entities should also keep in mind that untrained ''interpreters'' are more likely to make errors, violate confidentiality, and increase the risk of poor outcomes.[388] If the covered entity is unable to make the required assessment, relying on the accompanying adult is inappropriate.

Proposed paragraph (e)(3) prohibits a covered entity from relying on a minor child to interpret or facilitate communication, except as a temporary measure while finding a qualified interpreter 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 LEP individual immediately available—for example, directly following a serious car accident where, due to the nature of the injuries sustained, an LEP individual's critical care is a priority. Once the qualified interpreter has arrived, they must confirm or supplement the initial communications with the minor child. The use of children as interpreters raises the same concerns as those of an accompanying adult who is not qualified as an interpreter, but also poses other problems including exposing children to complex health care interactions for which they are not developmentally prepared, upsetting a family power dynamic, causing embarrassment, and conveying incorrect or incomplete information.[389]

Proposed paragraph (e)(4) prohibits reliance on staff other than qualified interpreters, qualified translators, or qualified bilingual or multilingual staff to communicate directly with LEP individuals.

Proposed paragraph (f) addresses standards for video remote interpreting (VRI) and is identical to former § 92.201(f) in the 2016 Rule.[390] The preamble to that rule states the purpose of developing VRI standards was to address concerns that the use of this technology may result in less comprehensible communication. The 2016 Rule preamble also explains that the VRI standards are designed to achieve parity with the regulation in the disability rights context.[391] These standards closely parallel those standards set forth in proposed § 92.202 regarding effective communication for individuals with disabilities, which, similar to the 2016 Rule, relies on standards in Title II of the ADA for the use of sign language interpreters.

The 2020 Rule does not address VRI services. The preamble explains that in place of VRI standards, the final rule adopts the four-factor analysis ''which will help covered entities balance competing considerations related to VRI quality standards.'' [392] The 2020 Rule RIA states that ''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 a clear audio transmission through the remote interpreting service.'' [393] The Department disagrees with this assessment. Performance standards are necessary so that VRI technologies do not result in ineffective communication. The plain terms of this provision do not require a covered entity to provide VRI but rather ensure that when such services are used, they must meet a quality standard.

Proposed paragraph (g) sets forth standards for audio remote interpreting services. Those standards, which are likewise important in order to have meaningful communication, are identical to those in the 2020 Rule at § 92.101(b)(3)(iii).[394]

Proposed paragraph (h) states that nothing in this section shall be construed to require an LEP individual to accept language assistance services. Identical language is contained in the 2020 Rule at § 92.101(c), and the 2016 Rule at former § 92.101(g).[395]

Effective Communication for Individuals With Disabilities (§ 92.202)

Proposed § 92.202 addresses requirements related to providing effective communication for individuals with disabilities. The 2020 Rule at § 92.102 and the 2016 Rule at former § 92.202 contain substantially the same requirements as this proposed section.

In proposed paragraph (a), we require a covered entity to take appropriate steps to ensure that communications with individuals with disabilities, and companions with disabilities, are as effective as communications with individuals without disabilities in its health programs and activities, incorporating the standards found at 28 CFR 35.130 and 35.160 through 35.164 of the regulation implementing Title II of the ADA. Proposed paragraph (a) is similar to the 2020 Rule at § 92.102(a), with the addition of ''companions'' to codify the Department's longstanding position that a covered entity's obligation to ensure effective communication extends not just to individuals with disabilities but to companions as well, if they are individuals with disabilities.[396]

[388] Gregory Juckett & Kendra Unger, *Appropriate Use of Medical Interpreters,* 90 A. Fam. Physician 476 (2014), *https://www.aafp.org/pubs/afp/issues/2014/1001/p476.html.*

[389] *See, e.g.,* Sunmin Lee et al., *Barriers to Health Care Access in 13 Asian American Communities,* 45 Am. J. Health Behav. 21, 22 (2010), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6628721/;* Wooksoo, *supra* note 106, at 289.

[390] 81 FR 31375, 31470–71 (May 18, 2016).

[391] *Id.* at 31418.

[392] 85 FR 37213.

[393] *Id.* at 37223.

[394] *Id.* at 37246.

[395] *Id.*

[396] Consistent with the Department's position in the 2016 Rule; 42 U.S.C. 12182(b)(1)(E)(Title III); 28 CFR 35.130(g) (Title II). *See generally,* U.S. Equal Emp't Opportunity Comm'n, Questions & Answers: Association Provision of the ADA (Oct. 17, 2005), *https://www.eeoc.gov/laws/guidance/questions-answers-association-provision-ada; cf. Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 277 (2d

Continued

Because we propose to incorporate all of the relevant Title II standards into proposed paragraph (a), including requirements that were enumerated in the 2020 Rule (*e.g.,* the requirements to provide auxiliary aids and services in a timely manner and free of charge, and to give primary consideration to the requests of individuals with disabilities when determining what types of auxiliary aids and services are necessary), we do not propose to enumerate these specific additional standards in this rule. This proposed section also clarifies that where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''covered entity'' shall apply in its place.

We propose in paragraph (b) to explicitly require covered entities to provide appropriate auxiliary aids and services to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such individuals an equal opportunity to benefit from the service in question. Once again, this paragraph is substantially similar to the 2020 Rule at § 92.102(b), which applied to recipients and State Exchanges. Because all covered entities, including the Department, are required to provide auxiliary aids and services, we propose to apply paragraph (b) to all covered entities, not just recipients and State Exchanges.[397]

We also note that in order to ensure a covered entity meets its obligations to provide both meaningful access and effective communication for LEP individuals with disabilities, it must comply with both proposed § 92.201 and proposed § 92.202. Auxiliary aids and services that are not provided in a language consistent with proposed § 92.201 do not satisfy the requirements of proposed § 92.202. For example, a covered entity that only offered auxiliary aids and services in English to an LEP individual with a disability may be in violation of both proposed § 92.201 and § 92.202.

The 2020 Rule defines ''disability,'' ''auxiliary aids and services'' and ''qualified interpreter'' at § 92.201; those definitions are now located in proposed § 92.4.

Accessibility for Buildings and Facilities (§ 92.203)

Proposed § 92.203 adds a general provision establishing that no qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity to which this part applies, consistent with the Department's Section 504 regulation covering federally assisted and federally conducted programs and activities.[398] The remainder of proposed § 92.203 incorporates the identical language found in the 2020 Rule at § 92.103, except that the definitions for ''1991 Standards,'' ''2010 Standards,'' and ''UFAS'' are now located in proposed § 92.4.

Accessibility of Information and Communication Technology for Individuals With Disabilities (§ 92.204)

Proposed § 92.204 addresses the accessibility of information and communication technology (ICT) for individuals with disabilities. This proposed section is substantially the same as § 92.104(a)–(b) of the 2020 Rule and former § 92.204 of the 2016 Rule. The 2020 Rule also defines ''information and communication technology'' at § 92.104(c), which we propose to define at proposed § 92.4.

With the advent of COVID–19 constraints placed on in-person services, the use of technology has become ever more critical. Covered entities have adapted creatively utilizing remote communications technologies to provide telehealth services, including audio, text messaging or video conferencing. Additionally, websites and online portals are serving as primary registration vehicles for obtaining COVID–19 tests and vaccines. In some instances, however, the use of inaccessible websites or online portals has resulted in access barriers for individuals with disabilities. For example, individuals with vision impairments who use screen reader software or persons with mobility impairments who have difficulty using a mouse, may not be able to access inaccessible online registration forms or navigate inaccessible vaccine websites.[399]

Many covered entities are currently relying on Section 508 standards promulgated by the Access Board or Web Content Accessibility Guidelines (WCAG) developed through the Worldwide Web Consortium's (W3C) Web Accessibility Initiative to ensure that their ICT is accessible to individuals with disabilities.[400] Additionally, multiple states have laws or policies addressing accessibility of ICT with which entities covered by those statutes must comply.[401] Over time, the feasibility of technological applications and solutions has continued to develop and dramatically change the way the public interacts with health programs and activities.

Proposed paragraph (a) requires covered entities to ensure that their health programs and activities provided through ICT 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. If an action required to comply with this subpart would result in such an alteration or burdens, a covered entity is required to take any other action that would not result in such an alteration or burdens but would nevertheless enable, to the maximum extent possible, individuals with disabilities to receive the benefits or services of the health program or activity provided by the covered entity.

Proposed paragraph (b) requires recipients and State Exchanges to ensure that their health programs and activities provided through websites and mobile applications comply with the requirements of Section 504 as interpreted in a manner consistent with Title II of the ADA. Both the 2020 Rule and the 2016 Rule have the same provision as it applies to recipient and State Exchange websites. We propose to modify this provision by extending it to mobile applications in addition to websites.

Given the heightened impact ICT has on individuals with disabilities in health programs and activities, as

Cir. 2009) (permitting associational discrimination claim under Section 504); *Falls* v. *Prince George's Hosp. Ctr.,* No. Civ. A 97–1545, 1999 WL 33485550, at *11 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under Section 504 when hospital required hearing parent to act as interpreter for child who was deaf).

[397] The Department is required to provide appropriate auxiliary aids and services under 45 CFR 85.51(a)(1) of this subchapter, which is incorporated by reference under proposed § 92.101(b)(1)(ii).

[398] 45 CFR 84.21 (federally assisted); § 85.41 (federally conducted).

[399] *See e.g.,* Press Release, U.S. Dep't of Just., Justice Department Secures Settlement with Rite Aid Corporation to Make Its Online Covid–19 Vaccine Portal Accessible to Individuals with Disabilities (Nov. 1, 2021), *https://www.justice.gov/usao-mdpa/pr/justice-department-secures-settlement-rite-aid-corporation-make-its-online-covid-19.*

[400] *See* Press Release, U.S. Dep't of Just., Justice Department Issues Web Accessibility Guidance Under the Americans with Disabilities Act (Mar. 18, 2022), *https://www.justice.gov/opa/pr/justice-department-issues-web-accessibility-guidance-under-americans-disabilities-act.*

[401] *Policy & Management: State Policy, Section508.gov, https://www.section508.gov/manage/laws-and-policies/state/* (last visited June 15, 2022).

evidenced by COVID–19, OCR is seeking comments on whether the Section 1557 rule should include a provision requiring covered entities to comply with specific accessibility standards, such as the Web Content Accessibility Guidelines (WCAG) developed by the Web Accessibility Initiative. Additionally, OCR seeks comments on whether to adopt a safe harbor provision under which covered entities that are in compliance with established specific accessibility standards are deemed in compliance with proposed paragraphs (a) and (b) of this section; whether OCR should require covered entities to comply with the most recent edition of a published standard; and the timeline necessary for covered entities to come into compliance with a new standard.

Requirement To Make Reasonable Modifications (§ 92.205)

Proposed § 92.205 requires covered entities to make reasonable modifications to 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. This provision is the same as § 92.105 of the 2020 Rule and former § 92.205 of the 2016 Rule. 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 implementing Title II of the ADA at 28 CFR 35.130(b)(7).[402]

Equal Program Access on the Basis of Sex (§ 92.206)

The Department proposes to include a section clarifying covered entities' obligation to ensure equal access to their health programs and activities without discrimination on the basis of sex, including pregnancy, sexual orientation, gender identity, and sex characteristics.[403] This provision primarily relates to covered entities that are directly engaged in the provision of health care services, such as hospitals, physical and mental health care providers, and pharmacies. While the 2016 Rule included a section on equal program access on the basis of sex, the 2020 Rule does not include an analogous provision. As Section 1557 is the only Federal civil rights law explicitly prohibiting sex discrimination in health programs and activities, the Department believes that it is beneficial to both covered entities and the public to have additional regulatory clarity. Nondiscrimination by covered entities in the provision or administration of health insurance coverage and other health-related coverage is addressed in proposed § 92.207.

Proposed § 92.206(a) describes a covered entity's general obligation to provide individuals equal access to the covered entity's health programs or activities without discrimination on the basis of sex. The Department proposes paragraphs (b)(1)–(4) to clarify certain types of discriminatory actions that would be prohibited for a covered entity in its provision of access to health programs or activities.

As is true for any claim of discrimination under this proposed rule, and consistent with the Department's standard practice for investigating such claims, OCR may use the tools of longstanding civil rights case law in analyzing claims of discrimination under paragraph (b). These tools include, but are not limited to, the multi-factor test articulated in *Arlington Heights,*[404] and the *McDonnell Douglas* [405] burden-shifting framework. Explained in great depth in the DOJ's Title VI Legal Manual, *Arlington Heights* is a method of proof that uses a number of different types of circumstantial evidence that, taken collectively, can demonstrate that the covered entity acted, at least in part, because of a protected basis. Under this test, evidence of disparate impact can be one piece of evidence that is considered in determining whether there is intentional discrimination. This framework is most commonly applied in cases alleging discrimination against a group.[406] The *McDonnell Douglas* burden-shifting framework, however, is most commonly applied in cases alleging discrimination in individual instances and is an inferential method of proof that is used to show that a defendant treated similarly situated individuals differently because of a protected basis.[407] Under *McDonnell Douglas,* where there is a prima facie case of discrimination against a covered entity, that covered entity must articulate a legitimate, nondiscriminatory reason for its actions. This legitimate, nondiscriminatory reason would be a defense against the claim of discrimination, unless it can be established that this reason is in fact a mere pretext for prohibited discrimination.

Proposed paragraph (b)(1) provides a general prohibition on the denial or limitation of health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded. The text of this proposed paragraph is similar to former § 92.206 of the 2016 Rule, which provided that ''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.'' [408] The 2020 Rule does not include a similar provision. The Department proposes to not include the word ''transgender'' in this proposed provision. This approach recognizes that the form of discrimination discussed herein may impact a range of individuals, including transgender people, individuals with intersex conditions, or people who may need these services but do not identify as transgender.

The Department's review of the literature indicates that this provision is warranted based on continued discrimination experienced by transgender and gender non-conforming individuals as they seek basic medical care. For example, transgender men who are pregnant experience significant forms of ''discrimination, stigma, and erasure'' when navigating pregnancy and prenatal care, particularly because pregnancy and childbirth are often treated as something exclusively experienced by cisgender women.[409]

Under this provision, a covered entity that routinely provides gynecological or obstetric care could not deny an individual a pelvic exam or pregnancy-related care because the individual is a transgender man or nonbinary person assigned female at birth, if the entity otherwise provides that care to cisgender individuals. Similarly, a community clinic that receives funding from the Department could not refuse to provide a transgender woman a prostate cancer screening because her sex is

[402] *See* discussion *supra* § 92.3 (addressing need for parity between Section 504 and the ADA).

[403] *See* discussion *supra* section II.B. (The 2020 Rule's Preamble Does Not Reflect Recent Developments in Civil Rights Law).

[404] *Vill. of Arlington Heights* v. *Metro. Housing Dev. Corp.,* 429 U.S. 252, 266–68 (1977).

[405] *McDonnell Douglas Corp.* v. *Green,* 411 U.S. 792 (1973).

[406] U.S. Dep't of Just., Title VI Legal Manual, sec. VI.B.2.

[407] *Id.* at sec. VI.B.3.

[408] *See* 81 FR 311375, 31471 (May 18, 2016).

[409] Margaret Besse et al., *Experiences with Achieving Pregnancy and Giving Birth Among Transgender Men: A Narrative Literature Review,* 93 Yale J. of Biology & Med. 517, 518 (2020).

listed female in her electronic health record, if the entity otherwise provides these screenings to cisgender individuals.

Proposed paragraph (b)(2) prohibits covered entities from denying or limiting a health care professional's ability to provide health services on the basis of a patient's sex assigned at birth, gender identity, or gender otherwise recorded. This provision recognizes that prohibited discrimination may take the form of attempted restrictions on individual providers, such as attending physicians, that have the effect of discriminating against patients, in addition to discriminatory actions that target patients directly. This is similar to Title VI's limited application to employment when a recipient's ''discrimination has a secondary effect on the ability of beneficiaries to participate meaningfully in and/or receive the benefits of a federally assisted program in a nondiscriminatory manner.'' [410]

Under this provision, a covered entity is also prohibited from punishing or disciplining a provider for providing clinically appropriate care where doing so would have the impact of limiting that provider's ability to provide such care on the basis of a patient's assigned sex at birth, gender identity, or gender otherwise recorded. As with all proposed paragraphs in this section, this provision does not require covered entities to perform services outside of their specialty area. However, restrictions by covered entities on the ability of providers to prescribe or provide care based on their patient's gender identity or sex assigned at birth would likely constitute prohibited discrimination in violation of this rule.

Proposed paragraph (b)(3) would prohibit a covered entity from applying any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than *de minimis* harm. The 2016 Rule provided, at former § 92.101(b)(3)(iv), that sex-specific health programs and activities were allowable only where the covered entity could ''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.'' The 2020 Rule repealed this provision, finding that the provision ''placed an unjustified burden on sex-specific health programs and activities conducted by private entities'' by adopting the Equal Protection standard that otherwise applies only to governmental actions that discriminate on the basis of sex.[411] The Department has considered the approaches taken in the 2016 and 2020 Rules and believes that while it is important to include a provision on this issue, the Constitutional standard is not the most appropriate for a regulation that applies to governmental and non-governmental actors. Rather, we believe the standard proposed now is the more appropriate approach.

Although differential treatment on the basis of sex is generally prohibited, the Department acknowledges that there are certain circumstances in which Section 1557 does not prohibit separation by sex or differential medical treatment on the basis of sex, namely, where it does not cause more than *de minimis* harm. A sex-based distinction that has only a minimal impact is not a form of ''discrimination'' that Congress intended to prohibit,[412] and an individual shall not be deemed subject to discrimination under this part by reason of the fact that an otherwise lawful health program or activity has chosen to utilize such sex-based distinctions consistent with the requirements of this rule. For example, the practice of assigning patients to dual-occupancy rooms in hospitals and in-patient treatment facilities on the basis of sex is not, standing alone, a form of discrimination.

However, the Department may still find that a covered entity violates Section 1557 if it implements the sex-based distinction in a way that constitutes discrimination, by imposing more than *de minimis* harm upon a particular individual. This is what Title IX requires.[413]

Discriminatory harm that is more than *de minimis* may include any adverse effect on a person's equal access to or participation in a covered entity's health program or activity based on sex. This provision does not, however, prohibit a covered entity from treating an individual for conditions that may be specific to their sex characteristics. For example, it would be permissible for an emergency department to treat a transgender man with a positive human chorionic gonadotropin (pregnancy) test as a pregnant person, even though pregnancy is generally associated with ''female'' sex characteristics, such as having a functioning uterus and ovaries.[414] Similarly, sex-specific clinical trials may be permissible based upon the scientific purposes of the study, *i.e.,* trials based on a particular sex-characteristic(s), such as those that test treatments for specific conditions or that evaluate differences in responses to treatment regimens among individuals with different sex characteristics. In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular health program or activity.

In particular, this provision would prohibit the adoption of a policy, or engaging in a practice, that prevents any individual from participating in a covered entity's health program or activity consistent with their gender identity. The 2016 Rule required that covered entities ''treat individuals consistent with their gender identity'' at former § 92.206; as discussed previously, the 2020 Rule preamble indicated that Section 1557 likely did not prohibit discrimination on the basis of gender identity as a form of prohibited sex discrimination, and therefore did not include a similar provision. The Department believes this provision is necessary to better effectuate Section 1557's purpose: to eliminate sex discrimination in a range of health programs and activities. Reading Section 1557's prohibition of sex discrimination consistently with the reasoning in *Bostock,* discrimination on the basis of gender identity necessarily involves consideration of an individual's sex—even if that term is narrowly defined—and Section 1557's prohibition covers discrimination on that basis. For example, a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman to share a room with a cisgender man,

[410] U.S. Dep't of Just., Title VI Legal Manual, sec. X.A.

[411] 85 FR 37160, 37196 (June 19, 2020).

[412] *See, e.g., Oncale* v. *Sundowner Offshore Servs., Inc.,* 523 U.S. 75, 81 (1998) (Title VII does not reach non-harmful ''differences in the ways men and women routinely interact with'' each other); *see also Burlington N. & Santa Fe Ry. Co.* v. *White,* 548 U.S. 53, 59–60 (2006) (''No one doubts that the term 'discriminate against' refers to distinctions or differences in treatment that injure protected individuals.''); *Threat* v. *City of Cleveland,* 6 F.4th 672, 678 (6th Cir. 2021) (''To 'discriminate' reasonably sweeps in some form of an adversity and a materiality threshold.'').

[413] *See Peltier* v. *Charter Day Sch., Inc.,* Nos. 20–1001, 20–1023, 2022 WL 2128579, at *16 (4th Cir. June 14, 2022) (en banc) (''for the plaintiffs to prevail under Title IX, they must show that . . . the challenged action caused them harm, which may include 'emotional and dignitary harm' '' (internal citation omitted)).

[414] *See, e.g.,* Daphna Strousma et al., *The Power and Limits of Classification—A 32-Year-Old Man with Abdominal Pain,* 380 N. Eng. J. Med. 1885 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7395710/pdf/nihms-1609250.pdf.*

regardless of how her sex is recorded in her insurance or medical records.[415]

Proposed paragraph (b)(4) prohibits a covered entity from denying or limiting health services sought for the purpose of gender-affirming care that the covered entity would provide to a person for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

This preamble generally uses the phrase ''gender transition or gender-affirming care.'' Relevant clinical guidelines acknowledge that not all individuals for whom such care is clinically appropriate will specifically identify as transgender, nor will all gender-affirming care specifically be related to transition from one binary gender to another.[416] For example, people seeking gender-affirming care may refer to their gender identity using terms other than ''transgender,'' such as ''nonbinary,'' ''gender nonconforming,'' ''genderqueer,'' or ''genderfluid.'' Individuals using any of these terms may have a gender dysphoria diagnosis and seek clinically appropriate gender-affirming care. A person's use of particular identity terminology is not determinative of whether the care in question is appropriate.

There also may be variations in the types of health services that are sought or are clinically appropriate for each person (*e.g.,* some people undergo hormone therapy as part of gender transition but do not seek any surgical care).[417] Additionally, some transgender people might not seek or require health interventions as part of their gender transition or gender-affirmation process. Nothing in this preamble or the regulatory text is intended to limit the application of provisions discussing gender-affirming care or transition-related care based on whether an individual uses particular terms to describe their gender identity or seeks only certain types of gender-affirming or transition-related care. The Department welcomes comments on this choice of terminology in the regulatory text, particularly from individuals seeking and providing such care.

Importantly, this provision does not require health care professionals to perform services outside of their normal specialty area; therefore a provider that declines to provide services outside its specialty area would have a legitimate, nondiscriminatory reason for its action. This is consistent with the Department's position under Section 504 regarding medical specialization. As explained in Appendix A to the Department's Section 504 implementing regulation, ''[a] burn treatment center need not provide other types of medical treatment to [individuals with disabilities] unless it provides such medical services to [persons without disabilities]. It could not, however, refuse to treat the burns of a deaf person because of his or her deafness.'' [418] This provision also does not compel a provider to prescribe a specific treatment that the provider decides not to offer after making a nondiscriminatory bona fide treatment decision. For example, a family practice covered by the rule would not be required to provide transition-related surgery where surgical care is not within its normal area of practice. Nor would the proposed rule require a pediatrician to prescribe hormone blockers for a prepubescent gender-nonconforming minor if that health care provider concluded, pursuant to a nondiscriminatory bona fide treatment decision, that social transition was the clinically indicated next step for that child.

By contrast, a gynecological surgeon may be in violation of the rule if they accept a referral for a hysterectomy but later refuse to perform the surgery upon learning the patient is a transgender man. If OCR were to receive a complaint in a case such as this, it would evaluate whether the provider had a legitimate basis for concluding that the surgery would not be clinically appropriate for the patient. If the surgeon invokes such a justification, OCR would make a determination as to whether the reason was a pretext for discrimination. OCR would also consider the application of Federal conscience and religious freedom laws, where relevant.

Proposed paragraph (c) provides that nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity reasonably determines that such health service is not clinically appropriate for that particular individual. However, a provider's view that no gender transition or other gender-affirming care can ever be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate. Paragraph (c) is consistent with the general principle in nondiscrimination law that covered entities facing allegations of discrimination have the opportunity to articulate a legitimate, nondiscriminatory basis for their challenged action or practice.[419] For example, a covered entity would not be required to perform a cervical exam on an individual who does not have a cervix, or to perform a prostate exam on an individual who does not have a prostate.

In evaluating whether a facially sex-neutral asserted basis is pretextual, OCR may consider whether a determination that care is not clinically appropriate is based on generally accepted scientific or medical standards. For example, a clinic could not raise a defense under this provision if they denied a transgender woman a prostate exam based on the provider's belief that prostate exams are never clinically appropriate for women, if in fact the particular patient has a prostate. Nor would this provision provide a defense to a provider denying testosterone therapy to an intersex woman with complete androgen insensitivity syndrome based on a categorical belief that such therapy is never clinically appropriate for women.[420]

Similarly, OCR recognizes that providers often need to make inquiries about a patient's sex-related medical history, health status, or physical traits related to sex in the course of providing care. Such inquiries are not per se discriminatory, even where they touch on intimate or sensitive matters, but should be related to the underlying condition. For example, it is not discriminatory—*i.e.,* it does not result in more than *de minimis* harm—for a provider treating a patient presenting with symptoms consistent with an ectopic pregnancy to inquire about the possibility that the patient could be pregnant, regardless of that patient's gender identity. However, where they are relevant to allegations of

[415] *See, e.g.,* Bulletin, U.S. Dep't of Health & Human Servs., The Brooklyn Hospital Center Implements Non-Discriminatory Practices to Ensure Equal Care for Transgender Patients (July 14, 2015), *https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/statement.pdf.*

[416] WPATH Standards, *supra* note 139, at pp. 8–9.

[417] *Id.*

[418] *See* 45 CFR pt. 84, app. A, subpt. F.

[419] *See, e.g., McDonnell Douglas Corp.* v. *Green,* 411 U.S. 792, 802 (1973); U.S. Dep't of Just., Title IX Legal Manual, sec. IV.A.1; *id.* at sec. VI.B.3; *see also Vill. of Arlington Heights* v. *Metro. Hous. Dev. Corp.,* 429 U.S. 252 (1977) (enumerating factors to be considered in evaluating whether a policy or practice is motivated by discriminatory intent); U.S. Dep't of Just., Title VI Legal Manual, sec. VI.B.2.

[420] *See* Wiebke Birnbaum et al., *Oestrogen Versus Androgen in Hormone-Replacement Therapy for Complete Androgen Insensitivity Syndrome: A Multicentre, Randomised, Double-Dummy, Double-Blind Crossover Trial,* 10 Lancet Diabetes Endocrinol. 771 (2018), *https://pubmed.ncbi.nlm.nih.gov/30075954/.*

discrimination, OCR may consider whether such inquiries are related to providing the care sought. Where such inquiries do not have a relationship to the care provided, or where they are made in a manner that is harassing, hostile, or evinces disregard for a patient's privacy, OCR may consider whether a provider's inquiries may be evidence of discrimination. For example, if a provider refused to provide treatment for a broken arm unless the patient answered questions about their history of genital surgery, OCR would consider whether there was any medical rationale for asking the question or whether it was mere pretext for discrimination, given the lack of connection between the question and the care being provided.[421] Similarly, a provider's repeated questions about whether a patient had had breast augmentation surgery could be considered as evidence of discrimination where such questions were unrelated to the care provided, especially if the manner of the questioning had other indicia of harassment. Where relevant, OCR will consider the totality of the circumstances in determining whether overbroad, irrelevant, or hostile inquiries may constitute evidence of discrimination.

Proposed paragraph (d) provides that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.

The Department believes that the provisions in proposed § 92.206 are consistent with, and in furtherance of, Section 1554 of the ACA, which prohibits the Secretary of HHS from promulgating a regulation that ''interferes with communications regarding a full range of treatment options between patient and the provider,'' or ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions.''[422] The provision as written supports and encourages health care providers' ability to discuss a full range of treatment options with their patients and in no way restricts providers' ability to share the range of risks and benefits associated with each treatment option. As discussed throughout this section, the provisions here do not compel a particular treatment for any given condition; rather, this section prohibits health care providers from discriminating against individuals on the basis of sex, including gender identity. Gender-affirming care, like all medical care, should follow clinical practice guidelines and professional standards of care.[423] Informed consent to any medical treatment is both a legal and ethical standard, regardless of the type of care, and serves as a basis for shared decision making.[424] When providing gender-affirming medical care for minors, informed consent involves discussions among providers, minors, and parents or guardians.[425]

We seek comment on this section, including whether it adequately addresses the forms of discrimination faced by individuals on the basis of sex (including pregnancy, sexual orientation, gender identity, and sex characteristics) when seeking access to and participating in health programs and activities; whether the proposed regulation text captures the policies set forth in this preamble; what sex-based distinctions, if any, should be permitted in the context of health programs and activities; and the standards for permitting such distinctions that do not result in more than *de minimis* harm.

We also invite comment on whether additional regulatory language should be added to specifically address the circumstance in which a provider offers a particular health treatment, service or procedure for certain purposes, but refuses to offer that same treatment, service or procedure for gender-transition or other gender-affirming care purposes because they believe it would not be clinically appropriate.

Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

Proposed § 92.207 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage. This proposed section would apply to all covered entities that provide or administer health insurance coverage or other health-related coverage that receive Federal financial assistance, and the Department in the administration of its health-related coverage programs. This is consistent with the 2016 Rule, which similarly prohibited discrimination in health-related insurance and other health-related coverage under former § 92.207, including in marketing practices and benefit design. The 2020 Rule repealed former § 92.207 in its entirety, stating that an additional or separate section on health insurance was not necessary.[426] Despite removing former § 92.207, the preamble to the 2020 Rule stated that OCR would continue to investigate discrimination in health insurance, including in benefit design.[427]

In rescinding former § 92.207, the 2020 Rule creates a lack of clarity for covered entities as to what constitutes prohibited discrimination in health insurance and health-related coverage.[428] This uncertainty creates confusion regarding what conduct is prohibited and renders Section 1557 less effective at combatting discrimination in health insurance and other health-related coverage, resulting in greater risk for covered entities and less protection for people who need health care and who are protected by Section 1557 against discrimination.

The statutory text of Section 1557 demonstrates Congress' intent to apply Section 1557 nondiscrimination requirements to health insurance and other health-related coverage where an entity receives Federal financial assistance and, therefore, the Department proposes to reinstate specific provisions related to nondiscrimination in health insurance and other health-related coverage in the Section 1557 rule. Robust enforcement of such nondiscrimination requirements for health insurance and other health-related coverage practices is critical to ensure individuals' ability to receive the health services that they need, unencumbered by discriminatory conduct. Such discriminatory conduct

[421] *See, e.g.,* David Oliver, '*Being Transgender Is Not a Medical Condition': The Meaning of Trans Broken Arm Syndrome,* USA Today (last updated Mar. 31, 2022), *https://www.usatoday.com/story/life/health-wellness/2021/07/27/trans-broken-arm-syndrome-what-it-how-combat-discrimination-health-care/8042475002/*; Douglas Knutson et al., ''*Trans Broken Arm*''*: Health Care Stories from Transgender People in Rural Areas,* 7 J. of Rsch. on Women & Gender 30 (2016), *https://journals.tdl.org/jrwg/index.php/jrwg/article/download/97/50.*

[422] 42 U.S.C. 18114(3), (4).

[423] *See e.g.,* WPATH Standards, *supra* note 139; Wylie Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,* 102 J. Clinical Endocrinology & Metabolism 3869 (2017), *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

[424] Am. Med. Ass'n, Informed Consent, *https://www.ama-assn.org/delivering-care/ethics/informed-consent* (*last* visited June 15, 2022).

[425] Hilary Cass, The Cass Review, Independent Review of Gender Identity Services for Children and Young People: Interim Report (2022), *https://cass.independent-review.uk/publications/interim-report/.*

[426] 85 FR 37160, 37201 (June 19, 2020).

[427] *Id.* at 37177, 37201.

[428] *See* Valarie K. Blake, *Health Care Civil Rights Under Medicare for All,* 72 Hastings L.J. 773, 800 (2021), *https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3925&context=hastings_law_journal* (stating the 2020 Rule ''eliminated all of the specific guidance on what counts as insurance discrimination, leaving the issue to OCR and the courts'').

reduces both access to care and the quality of care received on the basis of race, color, national origin, sex, age, or disability. The Department's proposal to reinstate the provisions is consistent not only with the ACA, but with the Administration's mission to enhance the health and well-being of all Americans.[429]

E.O. 14009, ''Strengthening Medicaid and the Affordable Care Act,'' states that it is the Administration's policy to ''protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American.'' [430] Of particular relevance to Section 1557, E.O. 14009 requires agencies to examine policies or practices that may undermine protections for people with pre-existing conditions under the ACA, may present ''unnecessary barriers'' to individuals seeking access to Medicaid or ACA coverage, and may reduce the affordability of coverage.[431] Additionally, E.O. 14070, ''Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage,'' states that agencies ''. . . shall review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage.'' [432] By specifying that health insurance and other health-related coverage offered through the Exchanges and Medicaid must be provided in a nondiscriminatory manner, proposed § 92.207 would strengthen access to health care and prevent unnecessary barriers in accessing coverage consistent with E.O. 14009 and E.O. 14070.

As discussed previously, historically marginalized communities disproportionally suffer from worse health outcomes and higher rates of discrimination in accessing health care than other communities.[433] By addressing the prevention of discrimination in health insurance and other health-related coverage, proposed § 92.207 also aligns with the Administration's goal of achieving health equity for these populations.[434]

Adopting proposed § 92.207, particularly paragraphs (b)(3)–(5), would establish specific provisions to protect gender-diverse individuals from discrimination in health insurance and other health-related coverage.

Proposed paragraph (a) provides a general nondiscrimination requirement, and proposed paragraph (b) provides specific examples of prohibited actions.

Proposed paragraph (b)(1) specifies that covered entities are prohibited from denying, cancelling, limiting, or refusing to issue or renew health insurance coverage or other health-related coverage, or denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability. This language is identical to the 2016 Rule and would prohibit health insurance issuers and other covered entities [435] from taking discriminatory actions related to coverage.

Proposed paragraph (b)(2) prohibits marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. This is consistent with both the 2016 Rule, which contained the same regulatory language, as well as the assurance in the preamble of the 2020 Rule that OCR will continue to investigate discrimination in health insurance or other health coverage benefit design, despite the repeal of former § 92.207.[436] Reinstating this provision will provide clarity and notice to covered entities and the public that Section 1557 continues to prohibit discriminatory marketing practices and benefit designs on the bases specified under Section 1557. This provision is independent of other regulations that separately prohibit discrimination in health insurance or other health-related coverage.[437] While these nondiscrimination requirements complement each other, covered entities are required to independently comply with all applicable regulations.

The terms ''benefit design'' and ''marketing practices'' encompass an array of features. To avoid being overly prescriptive or unintentionally inconsistent with other departmental regulations,[438] the Department does not propose defining these terms in this rule and intends to interpret them broadly. Examples of benefit design features include, but are not limited to, coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network.

Marketing practices would broadly include, for example, activities designed to encourage individuals to participate or enroll in particular health plans or certain types of plans, or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans.[439] For example, covered entities that avoid advertising in areas populated by a majority of people of color to reduce the

[429] *Mission Statement,* U.S. Dep't of Health & Human Servs., *https://www.hhs.gov/about/strategic-plan/introduction/index.html#mission* (last updated Mar. 28, 2022).

[430] 86 FR 7793 (Jan. 28, 2021) (revoking E.O. 13765, ''Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal,'' 82 FR 8351 (Jan. 20, 2017), which was cited as a justification for the 2020 Rule).

[431] *Id.* at 7794.

[432] 87 FR 20689, 20690 (Apr. 8, 2022).

[433] *See* discussion *supra* section II.D. (on advancing health equity).

[434] *See, e.g.,* E.O. 13985, 86 FR 7009 (2021).

[435] A variety of entities may be considered covered entities subject to proposed § 92.207, including but not limited to health insurance issuers, sponsors of group health plans, Medicare Advantage organizations, Medicare Part D plan sponsors, Medicaid managed care organizations, pharmacy benefit managers, third party administrators (as part of a covered entity's operations when it meets the criteria in paragraph (b) of the definition of ''health program or activity'' in proposed § 92.4), and the Department. For simplicity, we simply refer to ''health insurance issuers'' or ''issuers'' throughout the preamble, but please note that other covered entities may also be subject to the proposed section under discussion.

[436] *See* 85 FR 37177, 377201.

[437] *See, e.g.,* 42 CFR 422.100(f)(2)–(3), § 422.110 (Medicare Advantage); 42 CFR 423.2262(a)(1)(iv) (Part D); 42 CFR 438.3(d), (f) (Medicaid); 42 CFR 600.405(d) (Basic Health Program); 45 CFR 147.104(e) (group and individual health insurance markets); 45 CFR 155.120(c) (Exchanges); 45 CFR 156.125(a)–(b) (essential health benefits); 45 CFR 156.200(e), § 156.225(b) (qualified health plans).

[438] Other departmental and Federal regulations governing private health insurance and public health coverage refer to ''benefit design'' and ''marketing practices.'' *See, e.g.,* 45 CFR 147.104(e), § 156.20, § 156.125(a) (health insurance issuers); 45 CFR 156.110(d), § 156.125(a), § 156.200(b)(3), § 156.225(b) (qualified health plans); 45 CFR 156.110(d), § 156.111(b)(2)(v) (essential health benefits benchmark plans); 42 CFR 422.100(f)(3) (Medicare Advantage); 42 CFR 422.2260–15 (Medicare Part D marketing requirements); 42 CFR 423.882, § 423.894(d) (Medicare retiree prescription drug plans); 42 CFR 440.347(e) (Medicaid benchmark plans); 42 CFR 600.405 (Basic Health Program); 29 CFR 2510.3–40(c)(1)(iv)(A) (employee welfare benefit plan under Employee Retirement Income Security Act of 1974).

[439] For simplicity and for purposes of this preamble only, we use the term ''health plan'' or ''plan'' interchangeably to refer generally to health insurance coverage and other health coverage that is subject to this proposed rule. As used in this preamble, ''health plan'' or ''plan'' may include health insurance coverage offered in the group and individual markets, group health plans, Medicare Advantage plans, Medicare Part D plans, and Medicaid plans that are subject to this proposed rule. We do not intend ''health plan'' or ''plan'' to be regulatory terms in this proposed regulation or to replace any existing or proposed term in Federal law.

enrollment of people of color in their plans could violate this provision.[440]

By clarifying that health insurance and other health-related coverage must not employ discriminatory benefit design or marketing practices, proposed paragraph (b)(2) would further the ACA's goals of expanding access to affordable and quality health care and would be consistent with existing departmental regulations governing health insurance and other health-related coverage that similarly prohibit such discriminatory practices. The ACA prohibits the use of many formerly standard health insurance industry practices in many types of coverage that resulted in higher costs or denial of coverage or benefits for individuals with disabilities and others, including practices such as medical underwriting and premium rating[441] and pre-existing condition exclusions.[442] Its prohibition of discrimination in health-related coverage furthers the same goals.

We acknowledge that covered entities have discretion in designing their benefit packages, and we do not require entities to cover any particular procedure or treatment. When assessing complaints alleging discrimination in benefit design, OCR will evaluate on a case-by-case basis whether a particular design feature or coverage requirement is discriminatory. Where appropriate, OCR will determine if there is a legitimate, nondiscriminatory justification for the particular benefit design feature or coverage requirement. This justification cannot be pretext for discrimination. We elaborate further about how OCR will analyze claims of discrimination in benefit design later in this section.[443] As we articulate in that discussion,[444] this rule is not intended to prohibit covered entities from utilizing nondiscriminatory medical management techniques.

Proposed paragraphs (b)(3) through (5) address benefit designs that impermissibly limit coverage based on a person's sex at birth, gender identity, or gender otherwise recorded. The Department believes it is important to address discrimination faced by transgender individuals, including nonbinary and gender diverse individuals, in accessing coverage of health services.[445] Discrimination against transgender people in health insurance and other health-related coverage remains pervasive, especially for individuals who experience intersectional discrimination, such as individuals who experience both transphobia and racism.[446] As reported in a 2020 study of self-identified LGBTQ adults, 38 percent of transgender respondents—and 52 percent of transgender respondents of color—said that they had been denied hormone therapy coverage by their health insurer, and 43 percent reported being denied coverage for surgery for their transition.[447]

OCR believes the approach proposed in § 92.207(b)(3) through (5), which is similar to provisions in the 2016 Rule, will once again prove vital in helping to address discrimination faced by individuals whose sex assigned at birth is different from their gender identity in accessing coverage of health services, including health services that are medically necessary,[448] and is consistent with the legal principle that discrimination on the basis of sex includes discrimination on the basis of gender identity.[449] As discussed regarding how the Department will evaluate claims of discrimination under proposed § 92.206(b), the Department will look for direct or circumstantial evidence of discrimination when considering claims of intentional discrimination. Direct evidence may come in the form of an express classification (*e.g.,* explicit conditions for the receipt of benefits or services based on the sex of an individual) or statements from decisionmakers that express discriminatory intent. In the absence of such direct evidence, the Department would look for circumstantial evidence, including by using the *Arlington Heights* factors or *McDonnell Douglas* framework.

Proposed paragraph (b)(3) clarifies that it is prohibited discrimination to deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage to an individual based upon the individual's sex at birth, gender identity, or gender otherwise recorded.[450] The 2016 Rule provided a

[440] *See* Sidney D. Watson, *Section 1557 of the Affordable Care Act: Civil Rights, Health Reform, Race, and Equity,* 55 How. L.J. 855, 868 (2012), *https://heinonline.org/HOL/LandingPage?handle=hein.journals/howlj55&div=33&id=&page=.*

[441] 42 U.S.C. 300gg (prohibiting discriminatory premium rates by limiting rating factors to only include family size, geographic rating area, age, and tobacco use); 300gg–1 (requiring guaranteed availability of coverage to any individual or employer applying for coverage); 300gg–2 (requiring guaranteed renewability of coverage at the option of the plan sponsor or individual).

[442] 42 U.S.C. 300gg–3.

[443] *See* discussion *infra* under this section on Benefit Design.

[444] *See* discussion *infra* under this section on paragraph (c).

[445] As noted elsewhere in this preamble, although individuals with a gender identity that differs from their sex assigned at birth are commonly referred to as transgender, many individuals do not identify as such. Instead, some individuals may identify as nonbinary or gender diverse, meaning they do not identify with traditional binary gender or a single gender. Within these provisions, the term ''transgender'' is being used as an umbrella term to encompass individuals with transgender, nonbinary, gender diverse identities.

[446] Patterson, *supra* note 123, at p. 299.

[447] Gruberg, *supra* note 129, at p. 21; *see also* James, *supra* note 130, at p. 10 (2016) (25% of respondents with insurance reported experiencing insurance discrimination based on their gender identity, including being denied gender specific services and care not related to gender affirmation).

[448] The definition of medical necessity can vary. While the term ''medical necessity'' is not explicitly defined by CMS statute or regulation, Medicare provides coverage for items and services that are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' 42 U.S.C. 1395y(a)(1)(A). CMS further outlines medical necessity requirements for specific services in its various Medicare Policy Manuals. *See, e.g.,* Ctrs. for Medicare & Medicaid Servs., Medicare Program Integrity Manual, Chapter 6—Medicare Contractor Medical Review Guidelines for Specific Services, Sec. 6.1.4—Medical Review Process, p. 7 (2020), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c06.pdf* (stating ''[c]linical documentation that supports medical necessity may be expected to include: physician orders for care and treatments, medical diagnoses, rehabilitation diagnosis (as appropriate), past medical history, progress notes that describe the beneficiary's response to treatments and his/her physical/mental status, lab and other test results, and other documentation supporting the beneficiary's need for the skilled services being provided in the SNF.''). CMS defines ''medically necessary'' in the Summary of Benefits and Coverage (SBC) Template Uniform Glossary as ''[h]ealth care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms, including habilitation, and that meet accepted standards of medicine.'' Ctrs. for Medicare & Medicaid Servs., Glossary of Health Coverage and Medical Terms, p. 3 (2020), *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Uniform-Glossary-01-2020.pdf.* The American Medical Association defines ''medical necessity'' as ''[h]ealth care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.'' Am. Med. Ass'n, Definitions of ''Screening'' and ''Medical Necessity'' H–320.953 (2016), *https://policysearch.ama-assn.org/policyfinder/detail/H-320.953?uri=%2FAMADoc%2FHOD.xml-0-2625.xml*; *see also* WPATH Standards, *supra* note 139. While this regulation and preamble primarily use the term ''medical necessity,'' many covered entities also consider the related concepts of ''medical appropriateness'' or ''clinical appropriateness'' in making decisions about care and coverage, as can be seen in the definitions in this footnote. For the purposes of this rule, any such decisions must be nondiscriminatory, regardless of the label used.

[449] *Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731 (2020).

[450] Under the general nondiscrimination requirement in proposed § 92.207(a), a covered entity would be barred from denying coverage of any claim (not just for sex-specific services) on the basis that the enrollee's sex assigned at birth is different than their gender identity.

more specific prohibition, which provided that to deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on any health service that is ordinarily or exclusively available to persons of one sex when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the covered entity, is different from the one to which such services are ordinarily or exclusively available was prohibited sex discrimination. Such discrimination is similarly prohibited under this provision.

Although covered health plans routinely cover sex-specific preventive care services (*e.g.,* prostate and cervical cancer screenings) for cisgender individuals, some transgender individuals, due to their gender identity or because they are not enrolled in their health plan consistent with their sex assigned at birth, are denied coverage parity for the same preventive health services.[451] For example, under proposed § 92.207(b)(3), a health insurance issuer may not deny coverage for a transgender man who requires a mammogram screening, based on the fact that he is enrolled in the health plan as a man.[452] Nor could they deny him coverage of a uterine biopsy to identify potential uterine cancer because he is enrolled in the health plan as a man. Distinct from Section 1557, we remind covered entities that section 2713 of the Public Health Service Act (''PHS Act'') and its implementing regulations generally require coverage for certain recommended preventive health services without imposing cost-sharing requirements.[453]

We clarify that Section 1557 does not prohibit a covered entity from inquiring about an individual's relevant medical history and physical traits when necessary to determine the medical necessity of a health service for that individual. For example, in the same way a medical professional would not be prohibited from treating a pregnant transgender man for pregnancy,[454] a health insurance issuer (including its third party administrator activities, if applicable) may confirm that treatment related to pregnancy is medically necessary for an enrollee whose recorded sex is male.

We seek comment on this provision, including whether it sufficiently addresses the challenges transgender and gender nonconforming individuals are experiencing when seeking to access to medically necessary care due to a discordance between their sex assigned at birth and their sex as recorded by their issuer.

The Department, in paragraph (b)(4), proposes to prohibit a covered entity from having or implementing a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care.[455] This is consistent with the 2016 Rule at former § 92.207(b)(4), modified to include gender-affirming care. Some health plans continue to have a categorical ban on all gender-affirming care for transgender individuals as not medically indicated and as improper care to treat gender dysphoria, regardless of whether such care has been prescribed by a health care professional and despite widespread professional consensus to the contrary.[456]

Such categorical exclusions in covered plans both facially deny transgender individuals coverage access based on their gender identity and result in more than *de minimis* harm to the individuals; therefore they are prohibited discrimination on the basis of sex.[457] A covered entity's denial of coverage solely on the basis of one's sex assigned at birth—*i.e.,* if the individual was assigned a different sex at birth, such care coverage would not be denied—constitutes disparate treatment and is prohibited under this proposed rule because transgender individuals are the only individuals who seek transition-related care.[458] Additionally, a recent district court opinion found that ''it is impossible to determine whether a particular treatment is connected to'' gender affirming care without comparing [the person's] ''sex before the treatment to how it might be impacted by the treatment.''[459]

Nonetheless, some health plans still have broad exclusions of coverage for care related to gender dysphoria or associated with gender affirmation.[460]

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[451] Providers and issuers frequently formulate incorrect assumptions about transgender and gender non-conforming individual's bodies when assessing medical necessity for sex-specific preventive care. For example, cervical cancer risks for transgender men are sometimes erroneously assumed by providers to be lower than for cisgender women. Only 64% of respondents who retained a uterus were told by their providers to get screened for cervical cancer. *See* Mandi L. Pratt-Chapman & Adam R. Ward, *Provider Recommendations Are Associated with Cancer Screening of Transgender and Gender-Nonconforming People: A Cross-Sectional Urban Survey,* 5 Transgender Health 80, 83 (2020), *https://www.liebertpub.com/doi/10.1089/trgh.2019.0083.*

[452] *See also* FAQs about Affordable Care Act Implementation (Part XXVI), Q5 (May 11, 2015) (stating ''[w]hether a sex-specific recommended preventive service that is required to be covered without cost sharing under PHS Act section 2713 and its implementing regulations is medically appropriate for a particular individual is determined by the individual's attending provider. Where an attending provider determines that a recommended preventive service is medically appropriate for the individual—such as, for example, providing a mammogram or pap smear for a transgender man who has residual breast tissue or an intact cervix—and the individual otherwise satisfies the criteria in the relevant recommendation or guideline as well as all other applicable coverage requirements, the plan or issuer must provide coverage for the recommended preventive service, without cost sharing, regardless of sex assigned at birth, gender identity, or gender of the individual otherwise recorded by the plan or issuer''), available at *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/aca_implementation_faqs26.pdf* and *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf.*

[453] 45 CFR 147.130; 26 CFR 54.9815–2713; 29 CFR 2590.715–2713.

[454] *See* discussion *supra* proposed § 92.206(b)(3), (c).

[455] As noted in the discussion of § 92.206 above, this preamble uses the terms ''gender transition'' and ''gender affirmation'' interchangeably in discussing the range of care that transgender individuals (including those who identify using other terms, for example, nonbinary or gender nonconforming) may seek to treat gender dysphoria and support gender transition or affirmation. Because insurance coverage provisions and medical-necessity determinations more often use the term gender transition, within these provisions, the term gender affirmation encompasses gender transition, that is the terminology used in the text of the regulation. The use of the term ''gender transition'' in the regulation, however, is not intended to convey a narrower meaning than the term ''gender affirmation.''

[456] *See Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 987 (W.D. Wis. 2018) (noting that the American Medical Association, the American Psychiatric Association, the American Psychological Association, the American Counseling Association, the American Psychoanalytic Association, and the World Professional Association of Transgender Health, all recognize the medical necessity of transition related care for transgender people with gender dysphoria); *see also Flack* v. *Wisconsin Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1005 (W.D. Wis. 2019) (''For appropriate candidates, however, major medical organizations, including the American Medical Association, Endocrine Society, and American Psychiatric Association view gender-confirming surgeries as medically accepted, safe, and effective treatments for severe gender dysphoria.'').

[457] *See e.g., Flack,* 395 F. Supp. at 1001 (striking down Wisconsin Medicaid exclusion under Section 1557, Availability and Comparability Provisions of the Medicaid Act, and Equal Protection Clause of the U.S. Constitution); *Cruz* v. *Zucker,* 195 F. Supp. 3d 554, 571 (S.D.N.Y. 2016), *on reconsideration,* 218 F. Supp. 3d 246 (S.D.N.Y. 2016), *appeal withdrawn* (Dec. 30, 2016) (finding that a categorical ban on medically necessary treatments for a specific diagnosis, gender dysphoria, violates the Federal Medicaid Act's Availability Provision).

[458] *See* U.S. Dep't of Justice, Brief for the United States as Amicus Curiae in Support of Plaintiffs-Appellees, *Brandt* v. *Rutledge,* No. 21–2875, 11 (8th Cir. Aug. 23, 2021) (''Only persons who are transgender would seek these ''gender transition procedures,'' because only their gender identity differs from their ''biological sex'' (as defined by the Act).'').

[459] *Kadel* v. *Folwell,* No. 1:10–cv–00272, 2022 WL 2106270, at *19 (M.D.N.C. June 10, 2022).

[460] *See* Out2Enroll, Summary of Findings: 2021 Marketplace Plan Compliance with Section 1557, p.

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The Department proposes in paragraph (b)(5) to ensure that a covered entity does not impose discriminatory limits on coverage for specific health services related to gender transition or other gender affirming care, which would generally be the case if such limits are not applied when those same health services are not related to gender transition. The limits that could constitute discriminatory conduct prohibited by this paragraph include denying or limiting coverage, denying or limiting a claim for coverage, imposing additional cost sharing, or other limitations or restrictions on coverage on the basis of gender identity. For example, a health plan that excludes ''coverage for surgery, such as a vaginoplasty and mammoplasty'' for any enrollee whose sex assigned at birth is male ''while providing coverage for such medically necessary surgery'' for enrollees whose sex assigned at birth is female ''is discriminatory on its face.'' [461] Exclusions that limit care related to one class of gender transition or other gender-affirming care may also violate this provision.[462]

The proposed paragraphs (b)(3) through (5) do not: require covered entities to cover specific procedures or treatments for gender transition or other gender-affirming care that they do not otherwise cover under the plan.

In proposed paragraph (b)(6), the Department proposes an integration provision that prohibits covered entities from having or implementing a benefit design that does not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

The Department's existing Section 504 regulation includes an integration provision at 45 CFR 84.4(b)(2), which would be incorporated into Section 1557 at proposed § 92.101(b)(1). Section 504's integration provision provides that covered entities must provide services and programs in the most integrated setting appropriate to the needs of the qualified individual with a disability (referred to as the ''integration mandate''). The most integrated setting appropriate to the needs of an individual with a disability means a setting that enables individuals with disabilities to interact with individuals without disabilities to the fullest extent possible.[463] In 1999, the Supreme Court held in *Olmstead* v. *L.C.*[464] that the ADA's integration mandate prohibits the unjustified segregation of individuals with disabilities. Section 504's integration mandate creates the same set of obligations for entities that receive Federal financial assistance. In addition, health programs and activities must 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 making the modifications would fundamentally alter the nature of the service, program, or activity.[465]

Covered entities providing or administering health insurance or other health-related coverage are subject to the integration requirements under Section 504. Despite these obligations, covered entities may not be taking these requirements into account in their health-related coverage benefit design.[466] For example, literature shows that variation in benefit design, including reimbursement rates, impact whether individuals with disabilities exiting hospitals enter institutional, congregate, or otherwise segregated settings for post-acute care services, with payment practices and provider network design playing a greater role than clinical characteristics in some instances.[467]

OCR's intent in articulating this provision is to clarify that a benefit design that results in the unjustified segregation or institutionalization of qualified individuals with disabilities or that place such individuals at serious risk of unjustified institutionalization or segregation is prohibited disability discrimination.

For instance, benefit designs raising integration concerns may include those that: limit or deny access to services in

1 (2021), *https://out2enroll.org/wp-content/uploads/2020/11/Report-on-Trans-Exclusions-in-2021-Marketplace-Plans.pdf* (listing Bright Health, Ala., Ariz., Ill., N.C., Neb., Okla., S.C., Tenn.; United Healthcare, Ariz., Okla., Tenn.; Alliant, Ga.; Mercy Care, Ill. as offering plans that include categorical exclusions for all transition-related care). Until 2020, the percentage of issuers that affirmatively stated that some or all gender-affirming care for transgender individuals is covered had increased each year. There continues to be a presumption among some issuers, however, that except under narrow circumstances, such care is not medically necessary and therefore not covered. *Id.*

[461] *Fletcher* v. *Alaska,* 443 F. Supp. 3d 1024, 1031 (D. Alaska 2020) (Title VII); *see also Kadel,* No. 1:19–cv–00272, 2022 WL 2106270, at *28–*29 (Title VII).

[462] *See, e.g.,* Conn. Comm'n on Human Rights & Opportunities, Declaratory Ruling on Petition Regarding Health Insurers' Categorization of Certain Gender-Confirming Procedures as Cosmetic (Apr. 17, 2020), *https://www.glad.org/wp-content/uploads/2020/04/Dec-Rule_04152020.pdf* (discussing how depending on the policy or plan, the categorical exclusion of certain procedures for gender dysphoria discriminates on the basis of sex by denying equal access to certain medical procedures based on an individual's assigned sex. As such, a blanket policy exclusion for gender transition and related services is prohibited.). *See also Challenging Insurance Exclusions for Gender Affirming Medical Care,* GLBTQ Legal Advocates & Defenders, *https://www.glad.org/cases/challenging-insurance-exclusions-for-gender-affirming-medical-care* (last updated April 23, 2020).

[463] 28 CFR pt. 35, app. B (2011) (addressing § 35.130).

[464] *Olmstead* v. *L.C.,* 527 U.S. 581 (1999).

[465] 28 CFR 35.130(b)(7)(i); 45 CFR 92.105; *see also Olmstead,* 527 U.S. at 603–07.

[466] *See* Letter from the Bazelon Center for Mental Health Law to Robinsue Frohboese, Acting Dir., Office for Civil Rights, U.S. Dep't of Health & Human Servs. (June 7, 2021) (discussing how benefit design decisions can result in needless segregation of people with disabilities). The letter will be attached to the docket of this proposed rule as a supplemental material at *federalregister.gov.*

[467] Medicare Advantage and commercial health plan benefit designs that impose beneficiary cost-sharing, referral requirements or prior authorization requirements can restrict access to home health services. *See, e.g.,* Lacey Loomer et al., *Comparing Receipt of Prescribed Post-Acute Home Health Care Between Medicare Advantage and Traditional Medicare Beneficiaries: An Observational Study,* 36 J. Gen. Intern. Med. 2323 (2020), *https://link.springer.com/content/pdf/10.1007/s11606-020-06282-3.pdf* (finding that receipt of post-acute home health care was lower for Medicare Advantage enrollees compared with traditional Medicare enrollees, and that among Medicare Advantage enrollees, HMO plans with home health utilization restrictions (*i.e.,* cost sharing, pre-authorization, referral requirements) were less likely to receive prescribed home health); Laura Skopec et al., *Home Health Use in Medicare Advantage Compared to Use in Traditional Medicare,* 39 Health Affairs 1072 (2019), *https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01091* (finding Medicare Advantage enrollees were less likely to use home health care than traditional Medicare enrollees were and had shorter average home health spells, and suggesting that these differences in use and length of spell may be related to differences in how Medicare Advantage plans manage and pay for home health care); Scott E. Regenbogen et al., *Spending on Postacute Care After Hospitalization in Commercial Insurance and Medicare Around Age Sixty-five,* 38 Health Affairs 1505 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7795720/pdf/nihms-1659826.pdf* (finding that the benefit design practices of commercial insurers result in substantially less access to home health services for post-acute care than that which is available in fee-for-service Medicare). Such reductions in home health use do not necessarily violate the integration mandate if issuers simply reduce unnecessary service-provision without increasing risk of institutionalization and apply standard medical management techniques in a nondiscriminatory fashion as permitted under Section 1557 (proposed § 92.207(c)). However, a benefit design restricting access to home health services may raise concerns under the integration mandate if it leads to a serious risk of unjustified or unnecessary institutionalization of people with disabilities. Benefit design can also reduce the risk of institutionalization, including long-term institutionalization. *See, e.g.,* Amit Kumar et al., *Comparing Post-Acute Rehabilitation Use, Length of Stay, and Outcomes Experienced by Medicare Fee-for-Service and Medicare Advantage Beneficiaries with Hip Fracture in the United States: A Secondary Analysis of Administrative Data,* 15 PLoS Med., June 6, 2018, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6019094/pdf/pmed.1002592.pdf* (finding that benefit design and care management practices adopted by Medicare Advantage plans resulted in a lower risk of long-term institutionalization within a nursing home and a higher rate of successful discharge to the community relative to those used in fee-for-service Medicare).

the most integrated setting while making comparable services available in segregated or institutional settings; place additional terms and conditions on the receipt of certain benefits in integrated settings that are not in place within segregated or institutional settings; impose more restrictive rules or requirements for coverage for services in community-based settings than those applied to coverage for services in segregated or institutional settings; or set better reimbursement rates for a service or item for individuals in segregated settings than for individuals in community settings.[468] For example, an issuer covering a service or benefit (such as personal care or durable medical equipment) for individuals in institutional settings, but not covering the same service or benefit for individuals living in their own homes or in other community settings would violate this provision if the difference in coverage resulted in the unnecessary segregation of individuals with disabilities, or a serious risk of such segregation, unless it could show that modifications (to the coverage rule or policy) would fundamentally alter the nature of the service, program, or activity. We note that a state Medicaid program would generally not be required to provide a new benefit, because that would fundamentally alter the nature of the program. However, to the extent that a benefit, including an optional benefit, is already provided as part of the state's program, it must be offered in a manner that does not incentivize institutional services over community services.[469]

This provision will also be interpreted to apply both to circumstances where individuals with disabilities are unnecessarily segregated or institutionalized as a result of benefit design features, and circumstances where the benefit design places individuals with disabilities at serious risk of placement within an institution, congregate care setting, or other segregated settings through the coverage of or payment for services offered or provided in integrated settings relative to segregated ones, or through funding or service implementation practices within a benefit design set or administered by a covered entity that result in such a risk.[470] For example, a Medicare Advantage plan that requires prior authorization or step therapy to receive a medication in the community, but not in a skilled nursing facility, would be in violation of this provision if the discrepancy resulted in unnecessary segregation or a serious risk of unnecessary segregation and the distinction was not clinically appropriate. Similarly, if the plan relied on a pharmacy benefit manager (PBM) to administer prescription drug benefits, and the PBM employed utilization management techniques in the community that created greater barriers to accessing medication than in an institutional setting, the PBM may be in violation of this provision if the PBM is subject to this part.

This provision encompasses both the direct design of a benefit offered by a covered entity and indirect mechanisms that affect the implementation of a benefit design within the covered entity's control, such as utilization management practices, provider reimbursement, contracting out to third party-contractors such as PBMs, and quality measurement and incentive systems. Covered entities designing contracts with managed care organizations, PBMs, or other third-party entities taking on financial risk for the delivery of health services should carefully scrutinize their capitation, reimbursement, quality measurement, and incentive structures to ensure that they do not result in the unjustified segregation of individuals with disabilities or place individuals with disabilities at serious risk of unjustified segregation.

OCR seeks comment on the scope and nature of the benefit design features that result in unjustified segregation or institutionalization of qualified individuals with disabilities or place such individuals at serious risk of unjustified institutionalization or segregation. We are interested in feedback on the application of the integration mandate to a wide variety of health services and are particularly interested in comments on the application of the integration mandate to coverage of post-acute services, mental health services, and other services commonly provided by non-state payers (*i.e.,* health insurance issuers, self-insured group health plans, and other payers). We are also interested in feedback on the application of the integration mandate to the Medicaid program and its statutory framework at Title XIX of the Social Security Act. Specifically, we request input on how state Medicaid agencies are able to achieve compliance with the integration mandate through benefit design, such as through reimbursement, service scope, and service authorization that do not incentivize institutional services over community services. In addition, we request input on the amount of time needed to reach compliance with needed benefit design modifications.

Proposed paragraph (c) states that nothing in this section requires the coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements, such as medical necessity requirements, in an individual case.

Covered entities may employ reasonable medical management techniques, including medical necessity standards,[471] for determining coverage of a particular treatment based on whether it is medically appropriate under current generally accepted standards of care for an individual or whether the treatment is experimental or cosmetic, as long as the medical management standards are not discriminatory and are not otherwise prohibited under other applicable Federal and state law. When developed and used appropriately in a nondiscriminatory manner, medical necessity guidelines prevent unnecessary costs to covered entities and protect the safety of enrollees by ensuring that the requested treatment is safe and clinically appropriate for the particular enrollee. This determination involves a medical review of the patient's condition and the clinical appropriateness of the requested treatment in accordance with the covered entity's medical necessity guidelines. Such guidelines should be

[468] *See* Letter from the Bazelon Ctr. for Mental Health Law, *supra* note 466 (discussing how benefit design decisions can result in needless segregation of people with disabilities). The letter will be attached to the docket of this proposed rule as a supplemental material at *federalregister.gov.*

[469] *See, e.g., Radaszewski ex rel Radaszewski* v. *Maram,* 383 F.3d 599, 611 (7th Cir. 2004) (''Although a state is not obliged to create entirely new services or to otherwise alter the substance of the care that it provides to Medicaid recipients . . . the integration mandate may well require the State to make reasonable modifications to the form of existing services in order to adapt them to community-integrated settings.'')

[470] U.S. Dep't of Justice, Civil Rights Div., Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead v. L.C. (June 22, 2011), *https://www.ada.gov/olmstead/q&a_olmstead.htm. See also Fisher* v. *Oklahoma Health Care Authority,* 355 F.3d 1175 (10th Cir. 2003) (finding that it violates the integration mandate to restrict the number of prescription medications available to individuals enrolled in Medicaid home and community-based services to five per month while not applying such a cap to individuals in institutional settings); see also *Pashby* v. *Delia,* 709 F.3d 307 (4th Cir. 2021).

[471] *See supra* note 448 discussing definitions of medical necessity. *See also* 45 CFR 156.125(c) (CMS regulation prohibiting discrimination in essential health benefits stating that ''nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques'').

applied in a neutral manner and could raise concerns under this proposed rule if the guidelines establish more restrictive requirements for certain diseases or conditions without justification, for example, if the guidelines require a separate, more stringent review process only for mental health services.[472]

When OCR receives a complaint alleging that a denial of coverage was based upon prohibited discrimination rather than on a nondiscriminatory assessment of medical necessity, consistent with longstanding OCR practice, OCR will not conduct a general review of the medical judgment behind the denial for a specific individual. Rather, OCR's review will focus on the narrow question of whether the rationale for the denial was tainted by impermissible discriminatory considerations. Thus, OCR may require a covered entity to provide its medical necessity standards or guidelines; the clinical, evidence-based criteria or guidelines [473] relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination.

Claims of medical necessity that are not based upon genuine medical judgments will be considered evidence of pretext for discrimination. For example, issuers have historically excluded services related to gender-affirming care for transgender people as experimental or cosmetic (and therefore not medically necessary).[474] Characterizing this care as experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care.[475] Such exclusions are a form of disparate treatment discrimination, as they distinguish between care that is covered and care that is not solely by whether such care is provided as gender-affirming care for transgender people. Thus, categorical exclusions for gender-affirming care for transgender people that provide the basis for the exclusion as ''experimental'' would result in prohibited discrimination on the basis of sex. This is not to say that issuers must cover all services related to gender-affirming care for transgender individuals—or all medically necessary services generally. Issuers retain flexibility in designing their benefit packages, and this proposed rule would not require issuers to cover any particular benefit or to cover all medically necessary services. It does require, however, that issuers apply standards in a consistent, neutral, nondiscriminatory manner that does not limit or deny services to individuals based on a protected basis.

Proposed paragraph (c) also would not prohibit a covered entity from engaging in utilization management techniques applied in a neutral, nondiscriminatory manner. Utilization management techniques include prior authorization,[476] step therapy (or ''fail-first''),[477] and durational or quantity limits.[478] Utilization management controls, designed to control costs and ensure the clinically appropriate use of services,[479] are standard industry practices [480] that are permitted under Section 1557 as long as they are applied in a neutral, nondiscriminatory manner and are not otherwise prohibited under other applicable Federal and state law.[481] Excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate Section 1557.[482] For example, prescription drug formularies that place utilization management controls on most or all drugs that treat a particular condition regardless of their costs without placing similar utilization management controls on most or all drugs used to treat other conditions may be discriminatory under this section. Similarly, benefit designs that place utilization management controls on most or all services that treat a particular disease or condition but not others may raise concerns of discrimination. Where there is an alleged discriminatory practice or action, the covered entity would be expected to provide a legitimate, nondiscriminatory reason, based on clinical evidence, for the practice.

Finally, the Department proposes § 92.207(d) to explain that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.

Benefit Design

As discussed when addressing the requirements of proposed paragraph (b), OCR will apply basic nondiscrimination

[472] We note this practice may also violate the rules regarding non-quantitative treatment limitations applicable to group health plans and health insurance issuers under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Public Law 110–343, as amended, which is distinct from Section 1557 and not enforced by OCR. *See* 42 U.S.C. 300gg–26 (HHS); 29 U.S.C. 1185a (Department of Labor); 26 U.S.C. 9812 (Department of Treasury), and implementing regulations at 45 CFR 146.136, 29 CFR 2590.712, and 26 CFR 54.9812–1, respectively; *see also* U.S. Dep't of Labor, U.S. Dep't of Health & Human Servs., U.S. Dep't of the Treasury, 2022 MHPAEA Report To Congress: Realizing Parity, Reducing Stigma, and Raising Awareness: Increasing Access to Mental Health and Substance Use Disorder Coverage (2022), *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf*; U.S. Dep't of Labor, Self-Compliance tool for the Mental Health Parity and Addiction Equity Act (MHPAEA), p. 38 (2020), *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.*

[473] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27296–300 (May 6, 2022) (discussing newly promulgated 45 CFR 156.125(a), which states ''[a] non-discriminatory benefit design that provides [essential health benefits] is one that is clinically-based'').

[474] *See* discussion *supra* under this section on paragraphs (b)(3) through (4).

[475] *Id.*

[476] Medicare defines ''prior authorization'' as ''the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.'' 42 CFR 419.81 (Medicare definition of prior authorization for hospital outpatient department services). *See also* Ctrs. for Medicare & Medicaid Servs., Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services Frequently Asked Questions (FAQs), Q1 (Dec. 27, 2021), *https://www.cms.gov/files/document/opd-frequently-asked-questions.pdf.*

[477] Medicare defines ''step therapy'' for the Medicare Advantage Program as a ''utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary.'' 42 CFR 422.2.

[478] Durational or quantity limits place limits on the frequency or number of benefits to be provided, such as limiting therapy visits to once per week or limiting prescription drug coverage to a 30-day supply of a medication.

[479] *See, e.g.,* Ctrs. for Medicare & Medicaid Servs., Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services Frequently Asked Questions (FAQs), Q1 (Dec. 27, 2021), *https://www.cms.gov/files/document/opd-frequently-asked-questions.pdf* (explaining prior authorization ''ensures that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in the volume of covered services and improper payments'' and ''helps to make sure that applicable coverage, payment, and coding requirements are met before services are rendered while ensuring access to and quality of care'').

[480] *See generally* 42 U.S.C. 18120(1) (stating ''[n]otwithstanding any other provision in the [ACA], nothing in such Act (or an amendment made by such Act) shall be construed to (1) prohibit (or authorize the Secretary of Health and Human Services to promulgate regulations that prohibit) a group health plan or health insurance issuer from carrying out utilization management techniques that are commonly used as of March 23, 2010'').

[481] We note that, similar to medical necessity, discussed previously, these practices would generally be subject to the rules regarding non-quantitative treatment limitations applicable to group health plans and health insurance issuers, with respect to medical/surgical benefits and mental health and substance use disorder benefits, under MHPAEA, *see supra* note 472.

[482] *See generally* Stacey L. Worthy et al., *Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care,* 48 Loy. U. Chi. L.J. 1041 (2017), *https://lawecommons.luc.edu/luclj/vol48/iss4/8/.*

principles to the facts of the particular plan or coverage when analyzing allegations of discrimination under this section to determine if the challenged action is unlawful. Due to the fact-intensive nature of the analysis necessary to determine whether a particular benefit design is discriminatory under this section, we decline to include examples of per se discriminatory benefit design features in the proposed rule (other than categorical exclusions of all health services related to gender transition under proposed paragraph (b)(4), which, as discussed above, impermissibly single out an entire category of services based on an individual's gender identity).[483] However, we provide additional discussion here to demonstrate how OCR will approach investigations related to allegedly discriminatory benefit design.

Consistent with general principles in civil rights law, covered entities will have the opportunity to articulate a legitimate, nondiscriminatory justification for an alleged discriminatory action or practice. OCR will scrutinize the justification to ensure it is not a pretext for discrimination. When articulating a justification for a challenged action or practice that relies upon medical standards or guidelines, covered entities should be mindful that such standards and guidelines may be subject to additional scrutiny if they are not based on clinical, evidence-based criteria or guidelines.

As discussed in detail later in this section,[484] we propose to apply this part to all the operations of a covered entity that is principally engaged in the provision or administration of health programs or activities as described in paragraph (a) of the proposed definition of ''health program or activity,'' including a health insurance issuer's excepted benefits and short-term limited duration insurance products. Given the unique nature of these products, which are generally exempt from complying with any of the ACA's market reforms, we provide further analysis on how OCR proposes to investigate potential claims of discrimination challenging benefit design features in these products. OCR will consider the nature, scope, and contours of the specific plan at issue, and will evaluate on a case-by-case basis an alleged discriminatory design feature in light of the entity's stated coverage parameters.[485] Further, as discussed throughout this section, covered entities have the opportunity to articulate a legitimate, nondiscriminatory basis for their challenged action or practice.

Scope of Application and Application to Excepted Benefits and Short-Term Limited Duration Insurance

Proposed § 92.207 applies to all the operations of covered entities that provide or administer health insurance coverage or other health-related coverage, including health programs and activities that receive Federal financial assistance, and the Department in the administration of its health-related coverage programs, but would not apply to employers generally or in their provision of employee health benefits per proposed § 92.2(b). Examples of recipients that provide or administer health insurance coverage or other health-related coverage include health insurance issuers, Medicare Advantage organizations, Medicare Part D plan sponsors, and Medicaid managed care organizations.

Per paragraph (b) of the proposed definition of ''health program or activity'' under proposed § 92.4, we propose to apply this part to all the operations of any entity principally engaged in the provision or administration of health programs or activities described in paragraph (a) of the proposed definition of ''health program or activity,'' including a health insurance issuer. Thus, this proposed rule applies to all of a covered health insurance issuer's health programs and activities in the individual or group health insurance markets, including its offer of products through or outside of an Exchange. For example, an issuer participating in the Exchange and thereby receiving Federal financial assistance would be covered by the rule for its qualified health plans (QHPs) offered on the Exchange, as well as for its health plans offered outside the Exchange, including, for example, large group market plans,[486] grandfathered plans,[487] grandmothered plans,[488] excepted benefits,[489] and short-term limited duration insurance,[490] as well as for its operations related to acting as a third party administrator for a self-insured group health plan.

We recognize that many of these health insurance products are not subject to the ACA's market reforms codified in title XXVII of the PHS Act[491] in the same fashion as QHPs and other non-grandfathered health insurance coverage. For instance, large group market plans and grandfathered plans are subject to some but not all of the market reforms,[492] whereas excepted benefits and short-term limited duration insurance are generally exempt from all of the ACA's market reforms. Excepted benefits are statutorily defined benefits that are exempt from certain health care requirements, such as the ACA's market

[483] For examples of presumptively discriminatory benefit designs under CMS' essential health benefits nondiscrimination regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets, *see* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27301–05 (May 6, 2022) (providing the following illustrative examples of presumptively discriminatory practices under CMS' essential health benefits nondiscrimination regulations: (1) limitation on hearing aid coverage based on age; (2) autism spectrum disorder coverage limitations based on age; (3) age limits for infertility treatment coverage when treatment is clinically effective for the age group; (4) limitation on foot care coverage based on diagnosis (whether diabetes or another underlying medical condition); and (5) access to prescription drugs for chronic health conditions (adverse tiering)). We note these regulations are enforced by CMS and are distinct from Section 1557 and other civil rights laws enforced by OCR.

[484] *See* discussion *infra* under this section on Scope of Application and Application to Excepted Benefits and Short-Term Limited Duration Insurance.

[485] *Cf. Easley by Easley* v. *Snider,* 36 F.3d 297, 301–05 (3d Cir. 1994) (examining the ''essential nature of the program'' as intended by the state when determining that a state's Attendant Care Program did not discriminate against individuals with mental disabilities under the ADA by excluding adults with disabilities who were not mentally alert).

[486] 42 U.S.C. 300gg–91(2); 45 CFR 144.103.

[487] 42 U.S.C. 18011; 45 CFR 147.140.

[488] Grandmothered plans, also known as ''transitional'' plans, are certain non-grandfathered health insurance coverage in the individual and small group market that are not considered to be out of compliance with certain specified market reforms under certain conditions. *See* Ctrs. for Medicare & Medicaid Servs., Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[489] 42 U.S.C. 300gg–91(c); 45 CFR 144.103, § 146.145(b), § 148.220. Excepted benefits are a tri-Department matter regulated by the Departments of HHS, Labor, and the Treasury. In this proposed rule, we cite to HHS regulations, but note that the Departments of Labor and the Treasury have parallel regulatory citations.

[490] Short-term limited duration insurance is a type of health insurance coverage that is not subject to most of the provisions of title XXVII of the Public Health Service Act because it is specifically excluded from the definition of individual health insurance coverage in the PHS Act. 42 U.S.C. 300gg–91(b)(5). Short-term limited duration insurance is generally defined in Federal regulations as health insurance coverage issued under a contract that is effective for less than 12 months, and, taking into account renewals or extensions, has a duration of no longer than 36 months in total. 45 CFR 144.103. Short-term limited duration insurance is regulated by the Departments of HHS, Labor, and the Treasury. In this proposed rule, we cite to HHS regulations, but note that the Departments of Labor and the Treasury have parallel regulatory citations.

[491] 42 U.S.C. 300gg *et seq.*

[492] For example, large group market plans and grandfathered plans are not subject to the ACA's fair health insurance premiums (42 U.S.C. 300gg) or essential health benefits (42 U.S.C. 300gg–6) requirements.

reforms [493] and the nondiscrimination and portability requirements of HIPAA [494] when certain conditions are met, such as when benefits are supplemental to other medical benefits, when benefits are limited in scope, or when the benefits are provided as independent, non-coordinated benefits.[495] Examples of excepted benefits include limited scope vision insurance and limited scope dental insurance (though stand-alone dental plans sold through the Exchange are subject to certain QHP requirements [496]), long term care insurance, specified disease insurance, and Medicare supplemental health insurance (also known as ''Medigap'').

Public comments received from health insurance entities on the 2015 and 2019 NPRMs opposed application of Section 1557 nondiscrimination requirements to excepted benefits and short-term limited duration insurance.[497] The 2020 Rule narrowed the scope of application to health insurance at § 92.3(b)–(c) to provide that an issuer principally engaged in the business of providing health insurance shall not, by virtue of such provision, be covered by Section 1557 in all of its operations. This resulted in coverage of an issuer's operations only with respect to the particular line or sub-line of business for which the issuer receives Federal financial assistance, which effectively exempts coverage of excepted benefits and short-term limited duration insurance from the requirements established under the 2020 Rule.[498]

Unlike the 2020 Rule, this proposed rule would apply to all of an issuer's health programs and activities when an issuer is principally engaged in providing or administering health insurance coverage, or other health-related coverage as specified under paragraph (b) in the proposed definition of ''health program or activity'' under proposed § 92.4.[499] The fact that excepted benefits and short-term limited duration insurance are exempt from the ACA's market reforms because they are not intended to serve as comprehensive medical insurance does not negate that offering such insurance is a ''health program or activity.'' Further, the text of Section 1557 does not limit its protections only to health programs and activities that are subject to other provisions of the ACA. However, because the Department believes commenters' concerns about the application of Section 1557 to excepted benefits and short-term limited duration insurance warranted further consideration, we have provided additional discussion on how OCR proposes to analyze allegations of discrimination in such products in the preceding discussion on benefit design.

Application to Third Party Administrators

An issuer's or other entity's operations related to third party administrative services also would be subject to the rule when the issuer receives Federal financial assistance and is deemed to be principally engaged in the provision or administration of health programs or activities as described in paragraph (a) of the proposed definition of ''health program or activity'' under proposed § 92.4, which includes providing or administering health-related services, health insurance coverage, or other health-related coverage. We recognize that the Employee Retirement Income Security Act of 1974 (ERISA) requires group health plans to be administered consistent with their terms,[500] and, therefore, third party administrators are unable to change any discriminatory design features in the self-insured plans they administer to comply with Section 1557's requirements. In the 2016 Rule, we clarified that third party administrators were generally not responsible for the benefit designs of the self-insured group health plans they administer and that enforcing Section 1557 against a third party administrator for a group health plan with a discriminatory benefit design could result in holding a third party administrator liable for plan designs over which it had no control. Some third party administrators, however, are responsible for the development of the group health plan document or other policy documents that are ultimately adopted by the self-insured plan. Under these circumstances, where the discriminatory terms of the group health plan originated with the third party administrator rather than with the plan sponsor, the third party administrator could be liable for the discriminatory design feature under Section 1557.[501]

When OCR receives a complaint alleging discrimination in a self-insured group health plan administered by a covered entity acting as a third party administrator, we propose to adopt an approach similar to the 2016 Rule that takes into account the party responsible for the alleged discriminatory conduct.[502] We also restate the 2016 Rule's position that we will engage in a fact-specific analysis to evaluate whether a third party administrator is appropriately covered under Section 1557 as a recipient of Federal financial assistance in circumstances where the third party administrator is legally separate from the issuer that receives Federal financial assistance.

We also newly address that a third party administrator may be liable under this part when it is responsible for the underlying discriminatory plan design feature that is adopted by a group health plan. This modification is consistent with subsequent case law holding the same.[503] Accordingly, OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the plan sponsor or with the third party administrator. Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, OCR will process the complaint against the third party administrator because it is the entity responsible for the decision or other action being challenged in the complaint. For example, if a third party administrator denies a claim because the individual's name suggests that they are of a certain race or national origin, or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the entity responsible for the decision. In addition, OCR will pursue claims

[493] 42 U.S.C. 300gg–21(b)–(c), 300gg–63.

[494] Public Law 104–191, 100 Stat. 2548 (1996).

[495] 42 U.S.C. 300gg–91(c); 29 U.S.C. 1191b(c).

[496] *See, e.g.,* 45 CFR 155.1065, § 156.150.

[497] *See* 81 FR 31375, 31430–31 (May 18, 2016); 85 FR 37160, 37173 (June 19, 2020).

[498] *See* 85 FR 37173.

[499] We note that some health insurance issuers may be considered principally engaged in the business of providing health care as defined under the 2020 Rule at § 92.3(b), such as issuers offering HMO plans.

[500] ERISA Section 404(a)(1)(D) (29 U.S.C. 1104(a)(1)(D)).

[501] *See Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (holding that a third party administrator may be liable under Section 1557 for damages arising from discriminatory terms in a self-insured, employer-sponsored health plan that was under the sole control of the employer by refusing to construe ERISA to impair Section 1557 and finding that ''[n]othing in Section 1557, explicitly or implicitly, suggests that [third party administrators] are exempt from the statute's nondiscrimination requirements'').

[502] *See* 81 FR 31432.

[503] *See Tovar,* 342 F. Supp. at 954 (holding that a third party administrator may be liable under Section 1557 for damages arising from discriminatory terms in a self-insured, employer-sponsored health plan that was under the sole control of the employer by refusing to construe ERISA to impair Section 1557 and finding that ''[n]othing in Section 1557, explicitly or implicitly, suggests that [third party administrators] are exempt from the statute's nondiscrimination requirements'').

against the third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer. On the other hand, where the alleged discrimination relates to the benefit design of a self-insured group health plan that did not originate with the third party administrator, but rather with the plan sponsor, OCR will refer the complaint to the EEOC or the DOJ for potential investigation.

As part of OCR's enforcement authority, OCR has the option of referring or transferring matters to other Federal agencies with jurisdiction over the entity. For example, OCR will transfer matters to the EEOC where OCR lacks jurisdiction over an employer responsible for the benefit design of an employer-sponsored group health plan.[504] Complaints alleging discrimination in the Federal Employees Health Benefits (FEHB) Program, the Federal Employees Dental and Vision Insurance Program (FEDVIP), or the Federal Long Term Care Insurance Program (FLTCIP), would be referred to OPM. This Rule does not determine how or whether any other agency will investigate or enforce any matter referred or transferred by the Department.

Network Adequacy

Plan choices regarding provider networks may also violate Section 1557. Network plans offer medical care through a defined set of providers under contract with the issuer.[505] Subject to other applicable Federal and State laws, covered entities have discretion in developing their networks of providers, establishing reimbursement rates, and determining cost-sharing for in-network and out-of-network providers, including excluding coverage for out-of-network care. Covered entities using provider networks may be subject to certain network adequacy requirements governed by state and Federal law.[506] For example, CMS regulations contain network adequacy requirements for QHPs [507] (including essential community providers),[508] Medicare Advantage plans,[509] Medicare Part D prescription drug plans,[510] and Medicaid managed care plans.[511] Several of these regulations prescribe specific requirements, such as listing the types of providers that must be included in the network [512] and establishing time and distance standards for providers within a certain area.[513] QHPs that maintain a provider network must ensure that the provider network consisting of in-network providers includes essential community providers and is ''sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to ensure that all services will be accessible without unreasonable delay.'' [514] Starting in plan years 2023 and 2024 respectively, QHP issuers on a Federally-facilitated Exchange must meet time and distance standards, and appointment wait time standards established by the Federally-facilitated Exchange.[515]

Recognizing that network adequacy is regulated by other departmental regulations, we noted in the 2016 Rule, and again note here, that it is outside the scope of Section 1557 to establish uniform or minimum network adequacy standards. Nonetheless, the prevalence of narrow networks continues to grow as payers seek to keep premiums and costs low and drive patients to high-value providers.[516] Provider networks that limit or deny access to care for individuals with certain disabilities, such as by excluding certain providers from the network that treat high-cost enrollees, raise discrimination concerns.[517] Similarly, limited provider networks may require transgender enrollees to visit inexperienced providers in order to receive services, regardless of the potentially serious risks from receiving inadequate care. Enrollees are often required to prove why an in-network provider cannot meet their needs before their insurance will cover an out-of-network provider, raising additional obstacles that may cause particular harm to individuals with disabilities, transgender people, or other groups.[518]

We understand that an array of factors can affect the provider network design of a plan, including the geographic location of the service area, the number of available providers and specialists in the service area, reimbursement rates, the number of providers willing to contract with the payer, and the overall design of the plan as it relates to premiums. We recognize plans' and issuers' autonomy in developing their provider networks as part of their benefit design packages, consistent with existing state and Federal network adequacy and other laws, and we do not

[504] *See* 28 CFR 42.605.

[505] 42 U.S.C. 300gg–91(10); 45 CFR 144.103 (defining ''network plan'' as ''health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer'').

[506] Network adequacy refers to ''a health plan's ability to deliver the benefits promised by providing reasonable access to enough in-network primary care and specialty physicians, and all health care services included under the terms of the contract.'' *Network Adequacy,* Nat'l Ass'n of Ins. Comm'rs, *https://content.naic.org/cipr_topics/topic_network_adequacy.htm* (last updated Aug. 25, 2021).

[507] 45 CFR 156.230; *see also* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27322–34 (May 6, 2022) (discussing changes to network adequacy requirements for qualified health plans at 45 CFR 156.230); U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., 2023 Letter to Issuers in the Federally-facilitated Exchanges, pp. 10–17 (April 28, 2022), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2023-Letter-to-Issuers.pdf.*

[508] 45 CFR 156.235; *see also* 87 FR 27334–37 (discussing changes to the essential community providers requirements for qualified health plans at 45 CFR 156.235).

[509] *See e.g.,* 42 CFR 422.116; U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (2020), *https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf.*

[510] 42 CFR 423.120(a).

[511] 42 CFR 438.68 (requiring states to establish specified network adequacy requirements).

[512] 42 CFR 422.116(b) (Medicare Advantage); § 438.68(b) (Medicaid).

[513] 42 CFR 422.116(d) (Medicare Advantage); § 423.120 (a) (Part D); § 438.68(c) (Medicaid).

[514] 45 CFR 156.230(a)(1)–(2).

[515] 87 FR 27322–34 (discussing changes to network adequacy requirements for qualified health plans at 45 CFR 156.230).

[516] Steven Findlay, *In Search Of Insurance Savings, Consumers Can Get Unwittingly Wedged Into Narrow-Network Plans,* Kaiser Health News (Nov. 1, 2018), *https://khn.org/news/in-search-of-insurance-savings-consumers-can-get-unwittingly-wedged-into-narrow-network-plans/* (discussing 73% of plans offered through the Exchange in 2018 had restrictive networks compared to 54% in 2015).

[517] *See* Valarie K. Blake, *Restoring Civil Rights to the Disabled in Health Insurance,* 95 Neb. L. Rev. 1071, 1086 (2016), *https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=3046&context=nlr*; *see also,* Mark Shepard, Nat'l Bureau of Econ. Research, Working Paper 22600: Hospital Network Competition & Adverse Selection: Evidence from the Massachusetts Health Insurance Exchange (2016), *https://www.nber.org/papers/w22600* (finding high-cost enrollees favor plans that include expensive ''star'' hospitals in their network, which incentivizes plans not to include such hospitals in their networks); Subodh Potla et al., *Access to Neurosurgery in the Era of Narrowing Insurance Networks: Statewide Analysis of Patient Protection and Affordable Care Act Marketplace Plans in Arizona,* 149 World Neurosurgery e963 (May 2021), *https://pubmed.ncbi.nlm.nih.gov/33515792/* (finding 67 percent of counties in Arizona do not have access to outpatient neurosurgical care despite the presence of neurosurgical facilities in most counties); Stephen M. Schleicher et al., *Effects of Narrow Networks on Access to High-Quality Cancer Care,* 2 JAMA Oncology 427 (2016), *https://jamanetwork.com/journals/jamaoncology/article-abstract/2499779* (finding more than half of Exchange plans excluded four of eleven cancer centers).

[518] *Health Insurance—Choosing a Plan,* Transgender Legal Defense & Education Fund, Trans Health Project, *https://transhealthproject.org/trans-health-insurance-tutorial/choosing-plan/ (last updated July 16, 2020).*

propose to prescribe specific network adequacy requirements for covered entities under this rule. However, to ensure compliance with Section 1557, payers must develop their networks in a manner that does not discriminate against enrollees on the basis of race, color, national origin, sex, age, or disability.

We generally seek comment on how Section 1557 might apply to: provider networks; how provider networks are developed, including factors that are considered in the creation of the network and steps taken to ensure that an adequate number of providers and facilities that treat a variety of health conditions are included in the network; the ways in which provider networks limit or deny access to care for individuals on the basis of race, color, national origin, sex, age, or disability; and the extent to which the lack of availability of accessible medical diagnostic equipment in a provider network limits or denies access to care for individuals with disabilities.

In addition, the Department is also aware of growing concerns regarding impermissible discrimination in the application of value assessment methodologies used to set valuations for health care goods and services. Value assessment methodologies are an important tool to support health care payers in their coverage decisions and can significantly influence health benefit design, particularly through their use in price negotiations and value-based purchasing arrangements, as well as by informing utilization management decisions. However, where value assessment makes use of methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability (*e.g.,* by placing a lower value on life-extension for a group of individuals based on a protected basis or via inappropriate adjustment of clinical end points on the basis of a protected basis under Section 1557), they may violate this part. To that end, OCR seeks comment on the extent, scope and nature of value assessment methods that discriminate on the basis of race, color, national origin, sex, age, or disability. We are interested in feedback on the civil rights implications of value assessment across a wide variety of contexts, including utilization management, formulary design, price negotiations, alternative payment models and other relevant applications.

Finally, we seek comment on all aspects of this section. In particular, we seek comment on the anticipated impact of the proposed application to excepted benefits and short-term limited duration insurance plans when such products are offered by a covered entity; how the proposed rule's nondiscrimination requirements would impact the industry that offers excepted benefits and short-term limited duration insurance and the consumers who rely upon those products; the prevalence of excepted benefits and short-term limited duration insurance offered by covered entities and the standard industry practices under which such plans are designed and administered; and excepted benefits and short-term limited duration insurance plans' scope of coverage, types of exclusions and limitations, underwriting practices, premium setting, and actuarial or business justifications for industry practices (as applicable), that may raise concerns about discrimination under Section 1557.

Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)

The Department proposes in § 92.208 to provide that covered entities are prohibited from discriminating on the basis of sex in their health programs and activities with respect to an individual's marital, parental, or family status. The 2016 and 2020 Final Rules did not include a similar provision. This is not a new concept, however, as it is similar to the Department's Title IX regulation.[519]

The Department is proposing this provision to address issues OCR has encountered in its Section 1557 enforcement work. For example, OCR has resolved complaints against covered entities with policies of automatically assigning a male spouse as the guarantor when a female spouse received medical services, while not automatically assigning a female spouse as the guarantor when a male spouse received medical services.[520]

Proposed § 92.208 thus would provide that, in determining whether an individual satisfies any policy or criterion regarding access to its health programs or activities, a covered entity must not take an individual's sex into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.

The Department is also considering whether § 92.208 should include a provision to specifically address discrimination on the basis of pregnancy-related conditions.[521] Although neither the 2016 nor the 2020 Rules included a stand-alone provision prohibiting discrimination on the basis of pregnancy-related conditions, the 2016 Rule defined discrimination ''on the basis of sex'' to include, *inter alia,* discrimination on the basis of ''pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions.'' [522] The 2020 Rule does not include a definition of ''on the basis of sex'' at all, and therefore does not specifically include in the Section 1557 regulation a prohibition on discrimination on the basis of a person's ''termination of pregnancy'' or other conditions related to pregnancy.

The 2020 Rule does, however, prohibit discrimination on any of the ''grounds'' prohibited under Title IX,[523] and the Department's Title IX regulation, in turn, includes a provision expressly prohibiting discrimination on the basis of pregnancy-related conditions, including childbirth, false pregnancy, termination of pregnancy, and recovery therefrom.[524] Under this proposed rule, too, recipients would be required to comply with the specific prohibitions on discrimination found in the Department's Title IX regulations (including the regulation prohibiting discrimination on the basis of pregnancy-related conditions, including childbirth, false pregnancy, termination of pregnancy, and recovery therefrom).[525] In that respect it would not deviate from the 2016 or the 2020 Rule.

At the same time the Department promulgated the 2020 Rule, the Department amended its Title IX regulations to expressly include Title IX's statutory abortion neutrality provision,[526] and included in the Department's Section 1557 regulation a provision stating that the Section 1557 regulations may not be applied insofar as they would ''depart from, or contradict,'' Title IX exemptions, rights,

[519] 45 CFR 86.40(a).

[520] *Sex Case Summaries: Summary of Selected OCR Compliance Activities,* Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/sex-discrimination/index.html* (last updated Feb. 21, 2017).

[521] Such a provision would supplement proposed 92.101(a)(2), in which the Department proposes to define ''on the basis of sex'' to include pregnancy discrimination. *See* discussion *supra* § 92.101(a)(2).

[522] Former 45 CFR 92.4. Although the *Franciscan Alliance* court vacated the inclusion of the term ''termination of pregnancy'' in the 2016 Rule's definition of discrimination on the basis of sex, that vacatur neither applies to this current rulemaking, nor to a possible new final provision prohibiting discrimination on the basis of pregnancy-related conditions.

[523] 45 CFR 92.2(a), (b)(2).

[524] 45 CFR 86.40(a).

[525] *See* proposed 45 CFR 92.101(b).

[526] *See* 85 FR 37243 (promulgating 45 CFR 86.18(b)).

or protections.[527] This aspect of the 2020 Rule has been challenged in litigation.[528] This NPRM proposes repealing 45 CFR 92.6(b), the provision of the 2020 Rule challenged in those cases. The Department's view is that Section 1557 does not require the Department to incorporate the language of Title IX's abortion neutrality provision [529] into its Section 1557 regulation. This approach is consistent with the 2016 rule, which also did not incorporate Title IX's abortion neutrality provision. We acknowledge that the *Franciscan Alliance* court vacated the challenged provisions of the 2016 rule and reasoned that the Department was required to incorporate the language of Title IX's abortion neutrality provision; however, we disagree with that decision, which does not bind this new rulemaking.

The Department does note, however, that there are several other statutory and regulatory provisions related to the provision of abortions that may apply to an entity covered by Section 1557, and OCR will apply such provisions consistent with the law. For example, the Weldon Amendment forbids funds appropriated to HHS, among other Departments, from being ''made available to a Federal agency or program, or to a state or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.'' [530] The Coats-Snowe Amendment forbids discriminating against an entity that refuses to undergo training in performance or referrals for abortions.[531] The Church Amendment forbids requiring any individual ''to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions.'' [532] It also provides that an entity's receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act ''does not authorize any court or any public official or other public authority to require . . . such entity to . . . make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions.'' [533] The Church Amendment also prohibits discrimination against health care personnel related to their employment or staff privileges because they ''performed or assisted in the performance of a lawful sterilization procedure or abortion.'' [534] The same nondiscrimination protections also apply to health care personnel who refuse to perform or assist in the performance of sterilization procedures or abortion.[535] In addition, some of HHS' programs and services are specifically governed by abortion restrictions in the underlying statutory authority or program authorization.[536]

The Department also notes in this regard that the Emergency Medical Treatment and Active Labor (EMTALA) provides rights to individuals when they seek examination or treatment and appear at an emergency department of a hospital that participates in Medicare.[537] If that person has an ''emergency medical condition,'' the hospital must provide available stabilizing treatment, including abortion, or an appropriate transfer to another hospital that has the capabilities to provide available stabilizing treatment, notwithstanding any directly conflicting state laws or mandate that might otherwise prohibit or prevent such treatment.

The Department believes it could be beneficial to include a provision specifically prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination. We seek comment on whether and how the Department should do so. We also seek comment on what impact, if any, the Supreme Court decision in *Dobbs* v. *Jackson Women's Health Organization* [538] has on the implementation of Section 1557 and these regulations. In light of the *Dobbs* decision and E.O. 14076,[539] the Department also seeks comments on other approaches to ensure nondiscriminatory access to care under this provision.

Though Congress did not require the Department to incorporate the language of Title IX abortion-neutrality provision in its Section 1557 regulations, we seek comment on this approach and on other possible readings of the Title IX abortion-neutrality provision, as well as whether the Department should align its Title IX regulation regarding the abortion neutrality provision of Title IX with the 2000 ''Common Rule'' version of that regulatory provision that more than 20 agencies have long adopted.[540]

Nondiscrimination on the Basis of Association (§ 92.209)

Proposed § 92.209 prohibits discrimination against an individual on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual is

[527] *See* 45 CFR 92.6(b)).

[528] *See BAGLY* v. *U.S. Dep't of Health & Human Servs.,* No. 1:20–cv–11297 (D. Mass. Sept. 18, 2020); *New York* v. *U.S. Dep't of Health & Human Servs.,* No. 1:2–cv–00583 (S.D.N.Y. July 20, 2020). This NPRM proposes repealing 45 CFR 92.6(b), the provision of the 2020 Rule challenged in those cases.

[529] 20 U.S.C. 1688 (''Nothing in this chapter shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.'').

[530] Consolidated Appropriations Act, 2022, Public Law 117–103, div. H, title V General Provisions, sec. 507(d)(1) (Mar. 15, 2022). *See also, e.g.,* the ''Hyde Amendment,'' Consolidated Appropriations Act, 2021, Public Law 116–260, div. H, §§ 506–07, 134 Stat. 1182 (Dec. 27, 2020).

[531] 42 U.S.C. 238n(a).

[532] 42 U.S.C. 300a–7(d).

[533] *Id.* 300a–7(b)(2)(A).

[534] *Id.* 300a–7(c)(1). For more information, *see Guidance on Nondiscrimination Protections under the Church Amendments,* U.S. Dep't of Health & Hum. Servs., *https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html* (last updated Sept. 17, 2021).

[535] *Id.*

[536] *See, e.g.,* Title X of the PHS Act, 24 U.S.C. 300a–6; Section 1303(b)(4) of the ACA, 42 U.S.C. 18023.

[537] 42 U.S.C. 1395dd. For more information, *see* Letter to State Survey Agency Directors from U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Directors, Quality, Safety & Oversight Group and Survey & Operations Group (July 11, 2022), *https://www.cms.gov/files/document/qso-22-22-hospitals.pdf.*

[538] 142 S. Ct. 2228 (2022).

[539] 87 FR 42053 (July 8, 2022).

[540] See 65 FR 52869 (Aug. 30, 2000); see also, *e.g.,* 28 CFR 54.235(d)(1) (DOJ regulation). The agencies that have adopted the Common Rule include: Agency for International Development, 22 CFR pt. 229; Corporation for National and Community Service, 45 CFR pt. 2555; Department of Agriculture, 7 CFR pt. 15d.; Department of Commerce, 15 CFR pt. 8a; Department of Defense, 32 CFR pt. 196; Department of Energy, 10 CFR 1040; Department of Homeland Security, 6 CFR pt. 17; Department of Housing and Urban Development, 24 CFR pt. 3; Department of the Interior, 43 CFR pt. 41; Department of Justice, 28 CFR pt. 54; Department of Labor, 29 CFR pt. 36; Department of State, 22 CFR pt. 146; Department of Transportation, 49 CFR pt. 25; Department of the Treasury, 31 CFR pt. 28; Department of Veterans Affairs, 38 CFR pt. 23; Environmental Protection Agency, 40 CFR pt. 5; Federal Emergency Management Agency, 44 CFR pt. 19; General Services Administration, 41 CFR pt. 101–4; National Aeronautics and Space Administration, 14 CFR pt. 1253; National Archives and Records Administration, 36 CFR pt. 1211; National Science Foundation, 45 CFR pt. 618; Nuclear Regulatory Commission, 10 CFR pt. 5; Small Business Administration, 13 CFR pt. 113; and Tennessee Valley Authority, 18 CFR pt. 1317.

known to have a relationship or association. Longstanding interpretations of existing civil rights laws recognize claims of associational discrimination, where the basis is a characteristic of the harmed individual or an individual who is associated with the harmed individual.[541] In addition, the proposed prohibition on associational discrimination under Section 1557 corresponds with the specific prohibition of discrimination based on association with an individual with a disability under Section 504.[542]

The proposed provision is consistent with the former § 92.209 in the 2016 Rule, which was repealed by the 2020 Rule. OCR received many comments in response to the 2015 and 2019 NPRMs favoring the inclusion of an explicit provision in Section 1557 prohibiting discrimination on the basis of association.[543] Of particular note, the preamble to the 2020 Rule acknowledged that commenters opposed the repeal of former § 92.209 because: removing such protections would cause confusion; the lack of reference to associational discrimination in the regulatory text is inconsistent with existing case law; and specific protected populations are more susceptible to associational discrimination.[544]

The Department agrees that additional clarity is beneficial in this area, as OCR continues to see complaints alleging discrimination based on association. For example, under this provision, a medical practice may not refuse to see a prospective female patient based, in part, on the knowledge that the patient has a female spouse or partner because the refusal would be based on the sex of the prospective patient and on the sex of an individual with whom the patient is known to have a relationship or association.

Use of Clinical Algorithms in Decision-Making (§ 92.210)

Proposed § 92.210 states that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. This is a new provision, and this topic has not been addressed in previous Section 1557 rulemaking. The Department believes it is critical to address this issue explicitly in this rulemaking given recent research demonstrating the prevalence of clinical algorithms that may result in discrimination.[545] Further, the Department became aware that clinical algorithms in state Crisis Standards of Care plans used during the COVID–19 pandemic may be screening out individuals with disabilities, as discussed in more detail below. OCR believes that proposed § 92.210 would put covered entities on notice that they cannot use discriminatory clinical algorithms and may need to make reasonable modifications in their use of the algorithms, unless doing so would cause a fundamental alteration to their health program or activity. The intent of proposed § 92.210 is not to prohibit or hinder the use of clinical algorithms but rather to make clear that discrimination that occurs through their use is prohibited.

While covered entities are not liable for clinical algorithms that they did not develop, they may be held liable under this provision for their decisions made in reliance on clinical algorithms. Covered entities using clinical algorithms in their decision-making should consider clinical algorithms as a tool that supplements their decision-making, rather than as a replacement of their clinical judgment. By over-relying on a clinical algorithm in their decision-making, such as by replacing or substituting their own clinical judgment with a clinical algorithm, a covered entity may risk violating Section 1557 if their decision rests upon or results in discrimination.

Clinical algorithms are tools used to guide health care decision-making and can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models. End-users, such as hospitals, providers, and payers (*e.g.,* health insurance issuers) use these systems to assist with decision-making for various purposes. Clinical algorithms are used for screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources,[546] all of which affect the care that individuals receive. Recent studies have found that health care tools using clinical algorithms may create or contribute to discrimination on the bases protected by Section 1557, and as a result of their use by covered entities in their health care decision-making may lead to poorer health outcomes among members of historically marginalized communities.[547]

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[541] *See Kengerski* v. *Harper,* No. 20–1307, 2021 WL 3199225 (3d Cir. 2021) (a white plaintiff employee's claim is justiciable under an associational discrimination legal theory under Title VII of the Civil Rights Act of 1964, where his employer retaliated against him for complaining about a supervisor's racist remarks directed at the employee's biracial family member and other minority coworkers); *Kelleher* v. *Fred A. Cook, Inc.,* 939 F.3d 465 (2d Cir. 2019) (an employer's reaction to a non-disabled employee's reasonable accommodation request to care for disabled dependent can support an inference of associational discrimination); *McGinest* v. *GTE Serv. Corp.,* 360 F.3d 1103, 1118 (9th Cir. 2004) (case involving indirect comments in the workplace that crossed racial lines, noting that ''Title VII has . . . been held to protect against adverse employment actions taken because of the employee's close association with black friends or coworkers'') (internal citations omitted); *Johnson* v. *Univ. of Cincinnati,* 215 F.3d 561, 574 (6th Cir. 2001) (a plaintiff who is not a member of a recognized protected class nevertheless alleges a cognizable discrimination claim under Title VII and 42 U.S.C. 1981 if he alleges that he was discriminated against based on his association with a member of a recognized protected class); *Tetro* v. *Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.,* 173 F.3d 988, 994–95 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under Title VII based on his own race ''even though the root animus for the discrimination is a prejudice against the biracial child''); *Parr* v. *Woodmen of the World Life Ins.,* 791 F.2d 888, 892 (11th Cir. 1986) (''Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race.''); *Arceneaux* v. *Vanderbilt Univ.,* 25 Fed. App'x. 345 (6th Cir. 2001) (unpub'd) (treating sex discrimination as associational discrimination). *Cf. Loving* v. *Va.,* 388 U.S. 1 (1967).

[542] 29 U.S.C. 794a(a)(2); *see also McCullum* v. *Orlando Reg'l Healthcare Sys., Inc.,* 768 F.3d 1135, 1142 (11th Cir. 2014) (''[i]t is widely accepted that under both the [Rehabilitation Act] and the ADA, non-disabled individuals have standing to bring claims when they are injured because of their association with a disabled person.''); *Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 279 (2d Cir. 2009) (permitting associational discrimination claim under Section 504). *See also,* 42 U.S.C. 12182(b)(1)(E) (ADA); *Falls* v. *Prince George's Hosp. Ctr.,* No. 97–1545, 1999 WL 33485550 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under Title III of the ADA because hospital directly discriminated against parent by requiring hearing parent to act as interpreter for child who was deaf). *See generally* U.S. Equal Emp't Opportunity Comm'n, Association Q&A, *supra* note 396.

[543] *See* 81 FR 31375, 31438–39 (May 18, 2016); 85 FR 37160, 37199 (June 19, 2020).

[544] 85 FR 37199.

[545] *See infra* note 547.

[546] U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, Impact of Healthcare Algorithms on Racial Disparities in Health and Healthcare (Jan. 25, 2022), *https://effectivehealthcare.ahrq.gov/products/racial-disparities-health-healthcare/protocol*; *see also* Sahar Takshi, *Unexpected Inequality: Disparate-Impact from Artificial Intelligence in Healthcare Decisions,* 34 J. L. & Health 215, 219 (2021), *https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1580&context=jlh*; Christina Badaracco, Avalere, AI in Healthcare: 5 Areas in Which Artificial Intelligence Is Disrupting the Status Quo (Dec. 16, 2019), *https://avalere.com/insights/ai-in-healthcare-5-areas-in-which-artificial-intelligence-is-disrupting-the-status-quo* (including preventive health and risk assessment; diagnosis, precision medicine, drug development, and administration and care delivery).

[547] *See, e.g.,* Darshali A. Vyas et al., *Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms,* 383 N. Engl. J. Med. 874, 876–78 (Aug. 27, 2020); Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations,* 366 Science 447 (Oct. 2019), *https://doi.org/10.4018/978-1-7998-7888-9.ch001*; Donna M. Christensen et al., *Medical Algorithms Are Failing Communities of Color,*

Clinical algorithms commonly include clinical and sociodemographic variables and measures of health care utilization.[548] Race and ethnicity are often used as explicit input variables. Known as ''race correction'' or ''race norming,'' this practice adjusts an algorithm's output on the basis of a patient's race or ethnicity.[549] The use of ''race norming'' notably garnered public attention when the National Football League (NFL) pledged to end the practice of adjusting the results of cognitive functioning tests based on race to determine settlement amounts for brain injury claims of former NFL players.[550]

Another example of this practice can be found in the clinical tools that evaluate kidney function. Many such tools employ an estimation of glomerular filtration rate (eGFR) that includes race as a factor to reflect that Black people have been associated with higher levels of blood creatinine than white people.[551] The option for entering race in the eGFR is limited to a binary ''black/non-black'' option. The eGFR adjusts the score for Black patients, making their kidneys register as 16 percent healthier than white patients' kidneys even though Black Americans are about four times as likely to have kidney failure as white Americans and make up more than 35 percent of people on dialysis while representing only 13 percent of the U.S. population.[552] This race-based practice reduces the number of Black people placed on transplant lists and referred for kidney disease management, nephrology specialists, and dialysis planning.[553]

Reliance on the eGFR clinical algorithm may lead to discrimination against patients based on race and ethnicity. For example, discrimination concerns arise if a covered entity takes action based on the algorithmic output that results in less favorable treatment of a Black patient as compared to white patients with similar or healthier kidneys because an algorithm determined that a Black patient's kidney function is better than it actually is.[554] Concerns with the use of race in the estimation of GFR in the United States led the National Kidney Foundation and the American Society of Nephrology to create a task force on the issue, which ultimately recommended an approach that does not use race.[555]

The practice of ''race norming'' is not limited to eGFR, and also occurs in the following clinical tools: cardiology (to assess the risk of heart failure), cardiac surgery (to assess the risk of complications and death), obstetrics (to determine risks associated with vaginal birth after cesarean), urology (to assess the risk of kidney stones and urinary tract infections), oncology (to predict rectal cancer survival and breast cancer risk), endocrinology (to assess osteoporosis and fracture risks), and pulmonology (to measure lung function).[556] Covered entities must be mindful when using tools that rely on racial or ethnic variables to ensure their reliance on such tools does not result in discriminatory clinical decisions. We encourage covered entities to use updated tools that have removed or do not have known biases, such as the updated eGFR discussed above.

The Department notes that the use of algorithms that rely upon race and ethnicity-conscious variables may be appropriate and justified under certain circumstances, such as when used as a means to identify, evaluate, and address health disparities.[557] The Department also notes that the use of clinical algorithms may result in discriminatory outcomes when variables are used as a proxy for a protected basis and may also result from correlations between a variable and a protected basis.[558]

The use of clinical algorithms may also result in discrimination against individuals with disabilities and older adults. This issue surfaced in connection with Crisis Standards of Care and their use during the COVID–19 pandemic.[559] During the COVID–19 public health emergency, OCR received complaints and requests for technical assistance related to state Crisis Standards of Care plans. OCR worked with multiple states to address nondiscrimination in their Crisis Standards of Care plans and practices, including the states of Alabama, Arizona, North Carolina, Texas, Tennessee, and Utah.[560] Crisis Standards of Care are formal guidelines or policies adopted during an emergency or crisis that effect substantial change in usual health care operations and the level of care it is possible to deliver, which is made necessary by a pervasive or catastrophic disaster. In the effective marshaling of scarce resources, these standards may authorize the prioritization of scarce resources through means not permitted during non-crisis conditions. Crisis Standards of Care may include clinical algorithms in the form of flowcharts or other assessment tools intended to assist covered entities in prioritizing patients for scarce resources.

Health Affairs Blog (Sept. 9, 2021), *https://www.healthaffairs.org/do/10.1377/hblog20210903.976632/full/*; Kristine Gloria, Aspen Digital, Center for Inclusive Growth, Power and Progress in Algorithmic Bias (2021), *https://www.aspeninstitute.org/wp-content/uploads/2021/07/Power-Progress-in-Algorithmic-Bias-July-2021.pdf*.

[548] U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, Healthcare Algorithms, *supra* note 546.

[549] Vyas, *supra* note 547, at 876–78 (2020).

[550] Will Hobson, *How* ''*Race-Norming*'' *Was Built into the NFL Concussion Settlement,* Wash. Post (Aug. 2, 2021), *https://www.washingtonpost.com/sports/2021/08/02/race-norming-nfl-concussion-settlement/* (explaining race adjustments in cognitive test scores emanate from studies in the 1990s finding that some people of color, including Black people, performed worse than white people on cognitive tests).

[551] *See* Lundy Braun et al, *Racialized Algorithms for Kidney Function: Erasing Social Experience,* 286 J. Soc. Science & Med. 113548, p. 5 (2021), *https://doi.org/10.1016/j.socscimed.2020.113548* (discussing how race correction in eGFR is rooted in the assumption that Black individuals as a group are biologically distinct and have higher muscle mass than other groups, which was based on studies from the 1970s, without considering ''the complexity of national origin, socioeconomic status, the bodily effects of racism, and other unexplored considerations that influence kidney function'').

[552] *See, e.g.,* Nwamaka D. Eneanya et al., *Race-Free Biomarkers to Quantify Kidney Function: Health Equity Lessons Learned From Population Based Research,* 77 Am. J. of Kidney Diseases 667 (2021), *https://doi.org/10.1053/j.ajkd.2020.12.001*; Lesley A. Inker et al., *A New Panel-Estimated GFR, Including* β*2-Microglobulin and* β*-Trace Protein and Not Including Race, Developed in a Diverse Population,* 77 Am. J. of Kidney Diseases 673 (2021), *https://doi.org/10.1053/j.ajkd.2020.11.005*; Salman Ahmed et al., *Examining the Potential Impact of Race Multiplier Utilization in Estimated Glomerular Filtration Rate Calculation on African-American Care Outcomes,* 36 J. of Gen. Internal Med. 464, 466–67 (2021), *https://link.springer.com/content/pdf/10.1007/s11606-020-06280-5.pdf*.

[553] *See Ahmed, supra* note 552, at 467.

[554] *See, e.g.,* Compl., *Crowley* v. *Strong Mem. Hosp. of the Univ. of Rochester,* Civ. No. 21–cv–1078 (W.D.N.Y. Oct. 1, 2021) (22-year-old biracial individual with kidney disease brought a Title VI and Section 1557 action against hospital for using a medical algorithm (eGRF) to assess kidney health that added a race-specific multiplier for a Black person, which deemed him ineligible for a kidney transplant).

[555] *See* Cynthia Delgado et al., *A Unifying Approach for GFR Estimation: Recommendations of the NKF–ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease,* 79 Am. J. of Kidney Diseases 268, 283–284 (2022), *https://doi.org/10.1053/j.ajkd.2021.08.003* (recommending a new estimating equation for GFR that does not incorporate race).

[556] Vyas, *supra* note 547.

[557] *See e.g.,* Michelle Tong & Samantha Artiga, Kaiser Family Foundation, Issue Brief: Use of Race in Clinical Diagnosis and Decision Making: Overview and Implications (Dec. 9, 2021), *https://www.kff.org/racial-equity-and-health-policy/issue-brief/use-of-race-in-clinical-diagnosis-and-decision-making-overview-and-implications/*.

[558] *See, e.g.,* Obermeyer, *supra* note 547.

[559] *See* U.S. Dep't of Health & Human Servs., Office for Civil Rights FAQs for Healthcare Providers during the COVID–19 Public Health Emergency: Federal Civil Rights Protections for Individuals with Disabilities under Section 504 and Section 1557, Q4 (Feb. 4, 2022), *https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/disabilty-faqs/index.html*.

[560] *See Civil Rights and COVID–19, supra* note 184.

Use of such assessment tools for making resource allocation decisions that screen out or tend to screen out individuals with disabilities from fully and equally enjoying any health care service, program, or activity being offered, would violate Section 1557, unless the criteria used in such tools can be shown to be necessary for the provision of the service, program or activity being offered.[561] For example, to the extent an assessment tool considers a person's current health status, including a disability, for the purpose of determining a person's risk of in-hospital mortality as part of its resource allocation decision-making, such assessment tool might not violate this part, as consideration of short-term mortality risk is necessary for the implementation of Crisis Standards of Care. Similarly, assessment tools should not penalize patients for diminished long-term life-expectancy.[562] Assessment tools should not include categorical exclusions of certain types of disabilities, such as Down syndrome, when treatment would not be futile for individuals with that type of disability. As another example, Crisis Standards of Care may rely on instruments such as the Sequential Organ Failure Assessment (SOFA). The SOFA score is a scoring tool that assesses the performance of several organ systems in the body (neurologic, blood, liver, kidney, and blood pressure/hemodynamics) and assigns a score based on the data obtained in each category.[563] The higher the SOFA score, the higher the likely mortality, and consequently the higher likelihood of de-prioritization of the patient under many Crisis Standards of Care allocation frameworks. In addition, the SOFA score includes algorithmic scoring systems, such as the Glasgow Coma Scale, to assess the likelihood of mortality. The Glasgow Coma Scale considers whether a person's speech is comprehensible and whether they obey commands for movement. Someone with cerebral palsy may have difficulty speaking or moving as part of their underlying disability, which does not contribute to the short-term mortality outcomes the instrument is designed to assess. Adjustments must be made to ensure that such a person's pre-existing condition, and the symptoms of that condition, are not considered when using the Glasgow Coma Scale (whether within or outside of the SOFA) to evaluate whether they qualify for treatment or what priority they will receive in accessing scarce resources.[564] When using such tools, an entity may need to make reasonable modifications as required by proposed § 92.205 to its use of the assessment tool in order to avoid discrimination, unless doing so would cause a fundamental alteration.

In addition, the Department notes the existence of an emerging body of research showing that the SOFA and other prognostic scoring algorithms used in Crisis Standards of Care frequently overestimate Black mortality, resulting in greater de-prioritization of Black patients under Crisis Standards of Care.[565] The Department solicits comments on potential remedies to this issue and the larger topic of racial inequities in Crisis Standards of Care.

Research suggests that overly relying upon any clinical algorithm, particularly without understanding the effects of its uses, may amplify and perpetuate racial and other biases.[566] Accordingly, the Department strongly cautions covered entities against overly relying upon a clinical algorithm, for example, by replacing or substituting the individual clinical judgment of providers with clinical algorithms.[567] The individual clinical judgment of a provider should always be based on the specific needs and medical history of the patient being treated.[568] Covered entities that use clinical algorithms should consider using clinical algorithms as a tool to augment their decision-making but not as a replacement of clinical judgment. Covered entities that overly rely upon clinical algorithms run the risk of noncompliance with Section 1557 because such overreliance may result in discrimination.[569]

[561] *See also* 42 U.S.C. 12182(b)(2)(A)(i) (ADA).

[562] *See* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *supra* note 559, at Q4.

[563] *See generally* U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Preparedness & Response, Tech. Res. Assistance Ctr. & Info. Exchange (TRACIE), SOFA Score: What it is and How to Use it in Triage (Dec. 21, 2020), *https://files.asprtracie.hhs.gov/documents/asprtracie-sofa-score-fact-sheet.pdf.*

[564] *See* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *supra* note 559, at Q4. *See also Civil Rights and COVID–19, supra* note 184.

[565] *See, e.g.,* Deepshikha C. Ashana et al., *Equitably Allocating Resources During Crises: Racial Differences in Mortality Prediction Models,* 204 a.m. J. Respir. Crit. Care Med. 178 (2021), *https://pubmed.ncbi.nlm.nih.gov/33751910/* (finding use of SOFA in Crisis Standards of Care may lead to racial disparities in resource allocation); Benjamin Tolchin et al., *Racial Disparities in the SOFA Score Among Patients Hospitalized with COVID–19,* 16 PLoS ONE, Sept. 2021, at p. 2, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8448580/* (finding non-Hispanic Black patients but not Hispanic patients had greater odds of an elevated SOFA score when compared to non-Hispanic white patients); Shireen Roy et al., *The Potential Impact of Triage Protocols on Racial Disparities in Clinical Outcomes Among COVID-Positive Patients in a Large Academic Healthcare System,* 16 PLoS ONE, Sept. 2021, at p. 2, *https://pubmed.ncbi.nlm.nih.gov/34529684/* (finding Black patients had higher SOFA scores compared to patients of other races).

[566] *See, e.g.,* Letter from the Am. Med. Ass'n to David Meyers, Agency for Healthcare Research & Quality, p. 6 (May 3, 2021), *https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-5-3-Letter-to-Meyers-re-AHRQ-AI-RFI-(002).pdf* (in response to AHRQ's March 5, 2021 Request for Information on Use of Clinical Algorithms That Have the Potential to Introduce Racial/Ethnic Bias Into Healthcare Delivery) (stating that ''it is vital that all providers understand how the clinical algorithms they rely on to provide appropriate and equitable care in practice are developed. The need for such understanding is particularly acute as to how algorithms developed using artificial intelligence are trained in order to understand the appropriate uses for and limitations of such algorithms. Having this understanding will help ensure appropriate utilization of algorithms and encourage effective oversight by regulators, providers, and others. Over-reliance on any algorithm, particularly without an understanding of what its most effective uses are, can create a risk for amplifying and perpetuating biases that are present in the data, including any bias based in race or ethnicity.'').

[567] *See, e.g.,* Public Comment from the Am. Acad. of Family Physicians to the Office of Mgmt. & Budget, pp. 4–5 (June 23, 2021), *https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/equality/LT-OMB-EquityRFI-062321.pdf* (in response to OMB's May 5, 2021 notice on Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government) (stating that ''AI-based technology is meant to augment decisions made by the user, not replace their clinical judgement or shared decision making.''); Elliot Crigger & Christopher Khoury, *Making Policy on Augmented Intelligence in Health Care,* 21 a.m. Med. Ass'n, J. of Ethics 2, E188–191, Feb. 2019, at pp. 188–189, *https://journalofethics.ama-assn.org/article/making-policy-augmented-intelligence-health-care/2019-02* (discussing that health care AI should be a ''tool to augment professional clinical judgment, not a technology to replace or override it,'' and that organizations that implement AI systems ''should vigilantly monitor [the systems] to identify and address adverse consequences''); *see also* Nat'l Ass'n of Ins. Comm'rs, Principles on Artificial Intelligence (AI), p. 2 (2020), *https://content.naic.org/sites/default/files/inline-files/AI%20principles%20as%20Adopted%20by%20the%20TF_0807.pdf* (discussing that AI actors ''should implement mechanisms and safeguards . . . to ensure all applicable laws and regulations are followed, including ongoing (human or otherwise) monitoring, and when appropriate, human intervention'').

[568] *See* Elliot Crigger et al., *Trustworthy Augmented Intelligence in Health Care,* 46 J. Med. Sys., Jan. 2022, at p. 6, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8755670/pdf/10916_2021_Article_1790.pdf* (discussing that physicians are expected to understand the ''benefits, risks, indications, appropriateness, and alternatives'' of using AI tools and that tools should not be used if the physician is not able to understand enough about the tool to use it in their practice).

[569] *See* U.S. Dep't of Just., Algorithms, Artificial Intelligence, and Disability Discrimination in Hiring (2022), *https://beta.ada.gov/ai-guidance/* (discussing how algorithms and artificial intelligence in hiring technologies may result in unlawful discrimination against certain groups of applicants, including people with disabilities); U.S. Equal Emp't Opportunity Comm'n, The Americans with Disabilities Act and the Use of Software, Algorithms, and Artificial Intelligence to Assess Job

Clinical algorithmic tools are pervasive, and a covered entity may be unaware of any discrimination that may result from their reliance on such a tool. We note that individual providers are not likely to have designed the clinical algorithms that augment their clinical decision-making. However, covered entities are responsible for ensuring that any action they take based on a clinical algorithm does not result in discrimination prohibited by this part, irrespective of whether they played a role in designing the algorithm.[570] The fact that a covered entity did not design the algorithm or does not have knowledge about how the tool works does not alleviate their responsibility to ensure that they do not take actions that result in discrimination. In sum, this part does not hold covered entities liable for clinical algorithms that they did not develop but holds entities liable under this proposed section for the decisions they make in reliance on such algorithms.

We recognize that this is a complex and evolving area that may be challenging for covered entities to evaluate for potential violations of Section 1557. The Department shares a responsibility in working with recipients, Department components, and Title I entities to identify and prevent discrimination based upon the use of clinical decision tools and technological innovation in health care. Covered entities should take steps to ensure that the use of clinical algorithms does not result in discrimination on the basis of race, color, national origin, sex, age, or disability in their health programs and activities.[571] For example, covered entities may choose to establish written policies and procedures governing how information from clinical algorithms will be used in decision-making; monitor any potential impacts; and train staff on the proper use of such systems in decision-making.[572]

The American Medical Association (AMA) has been active in this area and issued a framework to guide the health care community in evaluating, integrating, using, and monitoring augmented intelligence systems that enhance capabilities of human decision-making with computational methods and systems (which includes clinical algorithm tools).[573] We recognize that ''augmented intelligence systems'' are different in scope from clinical algorithm tools, yet believe that the AMA research provides helpful guidance when covered entities are considering the use of clinical algorithm tools. The AMA framework suggests that providers should understand enough about the tools they are using in order to evaluate, select, and implement them, and should forgo the use of such tools if the provider does not adequately understand how they work.[574] Providers should also ensure that the tool addresses a meaningful clinical goal and works as intended, develop a clear protocol to identify and correct for potential bias, have the ability to override the tool, ensure meaningful oversight is in place for ongoing monitoring, and ensure clear protocols exist for enforcement and accountability, including a clear protocol to ensure equitable implementation.[575] When evaluating a tool, a provider should ask whether the tool was properly validated and validated for the specific case and use, whether it was tested in different populations to identify hidden bias, and whether it allows barriers to access to be found and rectified, among other things.[576]

Given the increasing reliance on clinical algorithms to inform decision-making in the area of health care, and the reality that the implementation of these tools may be discriminatory under Section 1557, the Department proposes § 92.210 to make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557. If OCR receives a complaint alleging discrimination resulting from the use of a clinical algorithm in decision-making against a covered entity, it will conduct a fact-specific analysis of the allegation. OCR's analysis will consider, among other things, what decisions and actions were taken by the covered entity in reliance upon a clinical algorithm in its decision-making, and what measures the covered entity took to ensure that its decisions and actions resulting from using a clinical algorithm were not discriminatory. OCR would, as required by statute and this proposed rule, work with the covered entity to achieve voluntary compliance.[577]

Applicants and Employees, EEOC–NVTA–2022–2 (2022), *https://www.eeoc.gov/laws/guidance/americans-disabilities-act-and-use-software-algorithms-and-artificial-intelligence* (discussing how employers' use of software that relies on algorithmic decision-making may violate existing requirements under Title I of the ADA).

[570] *See* U.S. Dep't of Just., *supra* note 569, at pp. 2–3 (discussing how an employer's use of algorithms and artificial intelligence in hiring technologies may still lead to unlawful discrimination even where the employer does not mean to discriminate); U.S. Equal Emp't Opportunity Comm'n, Americans with Disabilities Act and the Use of Software, *supra* note 569, at p. 6 (discussing how an employers' use of software that relies on algorithmic decision-making may violate existing requirements under Title I of the ADA and that an employer may still be liable under the ADA for its use of such tools even if the tools are designed or administered by another entity).

[571] For information on promising practices to reduce bias and discrimination in clinical algorithms, *see generally* Fed. Trade Comm'n, Using Artificial Intelligence and Algorithms (Apr. 8, 2020), *https://www.ftc.gov/news-events/blogs/business-blog/2020/04/using-artificial-intelligence-algorithms;* Fed. Trade Comm'n, Aiming for Truth, Fairness, and Equity in Your Company's Use of AI (Apr. 19, 2021), *https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai;* Fed. Trade Comm'n, Big Data: A Tool for Inclusion or Exclusion? (Jan. 2016), *https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf;* Nat'l Inst. of Standards & Tech., NIST Special Publ'n 1270, Towards a Standard for Identifying and Managing Bias in Artificial Intelligence (2022), *https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1270.pdf.;* Gen. Accountability Off., Artificial Intelligence: An Accountability Framework for Federal Agencies and Other Entities (2021), *https://www.gao.gov/assets/gao-21-519sp.pdf;* U.S. Food & Drug Admin., Good Machine Learning Practice for Medical Device Development: Guiding Principles (Oct. 2021), *https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles;* U.S. Equal Emp't Opportunity Comm'n, Americans with Disabilities Act and the Use of Software, *supra* note 569, at pp. 12–14; Takshi, *supra* note 546, at 234–39; Robert Bartlett et al., *Algorithmic Discrimination and Input Accountability Under the Civil Rights Acts* (preprint) (2020), *https://ssrn.com/abstract=3674665;* Nicol Turner Lee et al., Brookings Inst., Algorithmic Bias Detection and Mitigation: Best Practices and Policies to Reduce Consumer Harms (2019), *https://www.brookings.edu/research/algorithmic-bias-detection-and-mitigation-best-practices-and-policies-to-reduce-consumer-harms/;* Ada Lovelace Inst., AI Now Inst. & Open Gov't P'ship, Executive Summary: Algorithmic Accountability for the Public Sector, (2021), *https://www.opengovpartnership.org/wp-content/uploads/2021/08/executive-summary-algorithmic-accountability.pdf;* Ziad Obermeyer et al., Chicago Booth, Ctr. For Applied Artificial Intelligence, Algorithmic Bias Playbook (2021), *https://www.chicagobooth.edu/research/center-for-applied-artificial-intelligence/research/algorithmic-bias/playbook;* Mei Chen & Michel Decary, *Artificial Intelligence in Healthcare: An Essential Guide for Health Leaders,* 33 Healthcare Mgmt. F. 10, (2020), *https://pubmed.ncbi.nlm.nih.gov/31550922/;* Genevieve Smith & Ishita Rustagi, Berkeley Haas Ctr. for Equity, Gender, & Leadership, Mitigating Bias in Artificial Intelligence: An Equity Fluent Leadership Playbook (2020), *https://haas.berkeley.edu/wp-content/uploads/UCB_Playbook_R10_V2_spreads2.pdf; Trishan Panch et al., Artificial Intelligence and Algorithmic Bias: Implications for Health Systems, 9 J. Global Health, Dec. 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875681/pdf/jogh-09-020318.pdf.*

[572] *See, e.g.,* Takshi, *supra* note 546, at 234–35; Nat'l Inst. of Standards & Tech., NIST Special Publ'n 1270, *supra* note 571, at pp. 42–47; Gen. Accountability Off., *supra* note 571.

[573] *See, e.g.,* Crigger, *Trustworthy Augmented Intelligence in Health Care, supra* note 568.

[574] *Id.* at p. 6.

[575] *Id.*

[576] *Id.* at pp. 7–8.

[577] *See* 42 U.S.C. 2000d–1 (enforcement action may not be taken until the department has

Continued

OCR is committed to working with partners throughout the Department and other Executive Agencies [578] to develop responsive technical assistance to support covered entities in complying with their civil rights obligations. We seek comment on the inclusion of this provision; whether it is appropriately limited to clinical algorithms or should include additional forms of automated or augmented decision-making tools or models, such as artificial intelligence or machine learning; whether a provision such as this should include more specificity, including actions covered entities should take to mitigate potential discriminatory outcomes and what those actions should be; what promising practices could be used by covered entities to ensure that clinical algorithms are not discriminatory; and what type of technical assistance or guidance would be most helpful to covered entities for compliance with this section. We seek comment on what factors would be relevant to determine whether a covered entity is in violation of this provision and what possible defenses a covered entity may have when using a clinical algorithm in its decision-making that results in discrimination. We seek comment on governance measures, such as transparency mechanisms, reporting requirements, and impact assessments, that would assist in compliance with civil rights obligations. We also seek comment on what types of clinical algorithms are being used in covered health programs and activities; how such algorithms are being used by covered entities; whether they are more prevalent in certain health settings; when clinical algorithms and variables based on protected grounds under Section 1557 are useful (or not); and what mechanisms are in place or should be in place to detect, address, and remediate possible discriminatory effects of their usage. Finally, we seek comment requesting resources and recommendations on how to identify and mitigate discrimination resulting from the usage of clinical algorithms and other forms of automated decision-making tools and models.

Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

Proposed § 92.211 specifically addresses nondiscrimination in the delivery of health programs and activities through telehealth services. Telehealth is a means by which covered entities provide their health programs and activities, and this provision clarifies the affirmative duty that covered entities have to not discriminate in their delivery of such services through telehealth. This duty includes ensuring that such services are accessible to individuals with disabilities and provide meaningful program access to LEP individuals. Specifically, proposed § 92.211 provides that a covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age, or disability. Telehealth has not been addressed in previous Section 1557 rulemaking but has become widely used as a result of the COVID–19 pandemic.

As defined by the Health Resources Services Administration within the Department, telehealth means the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.[579] Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.[580]

Since 2016, the use of telemedicine at self-contained clinics and the use of telehealth provided to patients at home has grown significantly. This is particularly true of the use of telehealth at home due to the COVID–19 pandemic, with one recent study showing a 63-fold increase in Medicare telehealth utilization during the pandemic.[581] The increased availability of telehealth has been a benefit to many, including transgender individuals who have been able to access gender-affirming care without geographical constraints or fear of stigma and discrimination.[582] However, studies also indicate disparities in access based on race and disability. One study found ''significant'' racial disparities in telehealth use during the COVID–19 pandemic, which the authors believe may lead to the worsening of pre-existing health disparities.[583]

One study in 2016 on telehealth among Medicare beneficiaries found that individuals with disabilities accounted for 65 percent of telehealth use and 66 percent of all telehealth services. Individuals with disabilities using telehealth increased by 37.7 percent between the years 2014 and 2016. During that same time period, individuals with disabilities accounted for an increase of 53.7 percent of total telehealth services used.[584] Another more recent study looked at the broader

''determined that compliance cannot be secured by voluntary means''); 18116(a) (adopting the enforcement mechanisms provided for an available under Title VI).

[578] Many Federal agencies are taking steps to address discrimination in clinical algorithms and artificial intelligence. *See, e.g.,* U.S. Dep't of Health & Human Servs., Agency for Healthcare Research & Quality, 86 FR 12948 (Mar. 5, 2021) (Request for Information on the Use of Clinical Algorithms That Have the Potential to Introduce Racial/Ethnic Bias Into Healthcare Delivery); .S. Dep't of Justice, Nat'l Inst. of Just., *Predicting Recidivism: Continuing To Improve the Bureau of Prisons' Risk Assessment Tool, PATTERN* (Apr. 19, 2022), *https://nij.ojp.gov/topics/articles/predicting-recidivism-continuing-improve-bureau-prisons-risk-assessment-tool;* Kristen Clarke, Assistant Att'y Gen., U.S. Dep't of Just., Keynote Address at the Dep't. of Com.'s Nat'l Telecomm. & Info. Admin.'s Virtual Listening Session (Dec. 14, 2021), *https://www.justice.gov/opa/speech/assistant-attorney-general-kristen-clarke-delivers-keynote-ai-and-civil-rights-department;* Press Release, U.S. Equal Emp't Opportunity Comm'n, EEOC Launches Initiative on Artificial Intelligence and Algorithmic Fairness (Oct. 28, 2021), *https://www.eeoc.gov/newsroom/eeoc-launches-initiative-artificial-intelligence-and-algorithmic-fairness;* Bureau of Consumer Fin. Protection, Adverse Action Notification Requirements in Connection with Credit Decisions Based on Complex Algorithms (May 26, 2022), *https://www.consumerfinance.gov/compliance/circulars/circular-2022-03-adverse-action-notification-requirements-in-connection-with-credit-decisions-based-on-complex-algorithms/;* Bd. of Governors of the Fed. Reserve System, Bureau of Consumer Fin. Protection, Fed. Deposit Ins. Corp., Nat'l Credit Union Admin., & Office of the Comptroller of the Currency, 86 FR 16837 (Mar. 31, 2021) (Request for Information and Comment on Financial Institutions' Use of Artificial Intelligence, Including Machine Learning, Identifying Unlawful Discrimination as a Potential Risk of Using Artificial Intelligence); Fed. Trade Comm'n, Using Artificial Intelligence and Algorithms, *supra* note 571; Fed. Trade Comm'n, Aiming for Truth, Fairness, and Equity in Your Company's Use of AI, *supra* note 571; U.S. Dep't of Com., Nat'l Inst. of Standards & Tech., *supra* note 571.

[579] *What Is Telehealth?,* U.S. Dep't of Health & Human Servs., Health Rsch. & Servs. Admin. (last updated Mar. 2022), *https://www.hrsa.gov/rural-health/telehealth/what-is-telehealth.*

[580] *What Is Telehealth? How Is It Different from Telemedicine?, HealthIT.gov,* (last updated Oct. 17, 2019), *https://www.healthit.gov/faq/what-telehealth-how-telehealth-different-telemedicine.*

[581] Lok Wong Samson et al., U.S. Dep't of Health & Human Servs., Off. of the Assistant Sec'y for Planning & Evaluation, Issue Brief: Medicare Beneficiaries' Use of Telehealth Services in 2020: Trends by Beneficiary Characteristics and Location (2021), *https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf.*

[582] Ole-Petter R. Hamnvik et al., *Telemedicine and Inequities in Health Care Access: The Example of Transgender Health,* Transgender Health (pre-print) (2022), *https://www.liebertpub.com/doi/epdf/10.1089/trgh.2020.0122.*

[583] Robert P. Pierce & James J. Stevermer, *Disparities in the Use of Telehealth at the Onset of the COVID–19 Public Health Emergency,* J. Telemed & Telecare, Oct. 21, 2020, at p. 5, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578842/pdf/10.1177_1357633X20963893.pdf.*

[584] U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Information on Medicare Telehealth Report (2018), *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf.*

noninstitutionalized population and found that 39.8 percent of individuals with disabilities used telehealth during the second year of the pandemic.[585]

While there are benefits to be gained from telehealth for individuals with disabilities, including lower cost of care and transportation costs, lower exposure to communicable diseases, and access to specialized care including care provided across state lines, barriers persist around access.[586] Some of these challenges include inaccessible telehealth platforms and other barriers to communication with individuals who are deaf, blind, or have cognitive disabilities.[587] For example, telehealth platforms have been found to not have the ability to incorporate third-party services, including real-time captioning and any additional video feeds that may be required for the provision of qualified interpreters, direct service providers, or supportive decision makers.[588] Telehealth may also not include considerations for usability, compatibility with external assistive technology, and reduction on cognitive burden.[589] Remote patient monitoring devices used in telehealth may be challenging for individuals with manual dexterity or physical mobility disabilities to use.[590] Telehealth platforms may also not be compatible with screen reading software.[591] Purportedly accessible mobile health (mHealth) applications, such as applications offered by healthcare organizations to their patients, have also been found to be inaccessible.[592]

Although telehealth services are a means by which a covered entity may provide access to a health program or activity, and thus are clearly covered under Section 1557 and this proposed rule, the Department has decided to also include a specific provision regarding telehealth due to the increasing prevalence of telehealth and the numerous related accessibility challenges. Thus, covered entities are required to provide telehealth services in a manner that does not discriminate on a protected basis under Section 1557, including through the accessibility of telehealth platforms (proposed § 92.204) and by providing effective communication for individuals with disabilities through the provision of appropriate auxiliary aids and services (proposed § 92.202) and language assistance services for LEP individuals (proposed § 92.201). Such requirements broadly apply to all health programs and activities provided, including those via telehealth. Such services would include communications about the availability of telehealth services, the process for scheduling telehealth appointments, (including the process for accessing on-demand unscheduled telehealth calls), and the telehealth appointment itself.

OCR seeks comment on this approach and whether covered entities and others would benefit from a specific provision addressing accessibility in telehealth services, for individuals with disabilities and LEP individuals. We seek comment on what such a provision should include, and why the proposed provisions related to ICT, effective communication for individuals with disabilities, and meaningful access for LEP individuals are insufficient. Further, we seek comment on challenges with accessibility specific to telehealth and recommendations for telehealth accessibility standards that would supplement the ICT standards (proposed § 92.204) and effective communication requirements (proposed § 92.202) of this part. We encourage commenters to consider the range of technology available for accessing telehealth, including user-friendly design, as well as security and privacy requirements (for example, when using public Wi-Fi access).

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

Proposed § 92.301 provides that the enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part. This is consistent with the statutory text of Section 1557, which provides that ''[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.'' [593] Additionally, this provision is consistent with the 2016 Rule at former § 92.301(a) and § 92.5(a) of the 2020 Rule. Enforcement mechanisms include a private right of action, as recognized by the Supreme Court in *Cummings* v. *Premier Rehab Keller, P.L.L.C.*.[594]

Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

In proposed § 92.302, the Department specifically addresses the application of Federal conscience and religious freedom laws. This is a newly proposed provision, as neither the 2016 nor 2020 Rule provided a specific means for recipients to notify the Department of their views regarding the application of Federal conscience or religious freedom laws.

Proposed paragraph (a) provides that a recipient may raise with the Department its belief that the application of a specific provision or provisions of this regulation as applied to it would violate Federal conscience or religious freedom laws. Such laws include but are not limited to the Coats-Snowe Amendment, Church Amendments, RFRA, section 1553 of the ACA, section 1303 of the ACA, and the Weldon Amendment. Recipients are also reminded that they can file complaints regarding Federal conscience laws with OCR, as provided in 45 CFR part 88.

Proposed paragraph (b) provides that once OCR receives a notification pursuant to proposed paragraph (a), OCR shall promptly consider those views in responding to any complaints

[585] Carli Friedman & Laura VanPuymbrouck, *Telehealth Use by Persons with Disabilities During the COVID–19 Pandemic,* 13 Int'l J. Telerehabilitation 2 (2021), *https://doi.org/10.5195/ijt.2021.6402*.

[586] Thiru M. Annaswamy et al., *Telemedicine Barriers and Challenges for Persons with Disabilities: COVID–19 and Beyond,* 13 Disability Health J., July 9, 2020, at p. 2, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7346769/pdf/main.pdf;* Daniel Young & Elizabeth Edwards, *Telehealth and Disability: Challenges and Opportunities for Care,* Nat'l Health Educ. Law Program, (May 6, 2020), *https://healthlaw.org/telehealth-and-disability-challenges-and-opportunities-for-care/*.

[587] Annaswamy, *supra* note 586, at p. 2; Young, *supra* note 586; Rupa S. Valdez et al., *Ensuring Full Participation of People with Disabilities in an Era of Telehealth,* 28 J. Am. Med. Inform. Ass'n 389 (Feb. 2021), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7717308/*.

[588] Valdez, *supra* note 587.

[589] *Id.;* Daihua X. Yu et al., *Accessibility Needs and Challenges of a mHealth System for Patients with Dexterity Impairments,* 12 Disabil. Rehabil. Assist. Technol. 56–64 (2015), *https://doi.org/10.3109/17483107.2015.1063171;* Erin Beneteau et al., *Telehealth Experiences of Providers and Patients Who Use Augmentative and Alternative Communication,* 29 J. Am. Med. Inform. Ass'n 481–488 (2022), *https://doi.org/10.1093/jamia/ocab273*.

[590] Annaswamy, *supra* note 586, at p. 2.

[591] *Id.;* Young, *supra* note 586; Valdez, *supra* note 587.

[592] Keith M. Christensen & Jill Bezyak., Rocky Mountain ADA Center, Telehealth Use Among Rural Individuals with Disabilities (2020), *https://rockymountainada.org/sites/default/files/2020-02/Rural%20Telehealth%20Rapid%20Response%20Report.pdf;* Lauren R. Milne et al., *The Accessibility of Mobile Health Sensors for Blind Users,* 2 J. Tech. Persons Disabilities 166–175 (2014), *https://scholarworks.calstate.edu/downloads/xs55mg57v#page=173*.

[593] 42 U.S.C. 18116.

[594] 142 S. Ct. 1562, 1569–70 (2022) (''it is 'beyond dispute that private individuals may sure to enforce' [Section 504 and Section 1557]'').

or otherwise determining whether to proceed with any investigation or enforcement activity regarding that recipient's compliance with the relevant provisions of this regulation. Any relevant ongoing investigation or enforcement activity regarding the recipient shall be held in abeyance until a determination has been made under paragraph (c). Considering recipients' religious- or conscience-based concerns in the context of an open case (*i.e.,* when OCR first has cause to consider the recipient's compliance), will allow OCR to make an informed, case-by-case decision and, where applicable, protect a recipient's conscience or religious freedom rights. Similarly, holding ongoing investigations and enforcement activity in abeyance is designed to alleviate the burden of a recipient having to respond to an investigation or enforcement action until a recipient's objection has been considered by OCR.

Proposed paragraph (c) makes clear OCR's discretion to determine at any time whether a recipient is wholly exempt from or entitled to a modification of the application of certain provisions of this part, or whether modified application of the provision is required under a Federal conscience or religious freedom law. Proposed paragraph (c) requires that, in determining whether a recipient is exempt from the application of the specific provision or provisions raised in its notification, OCR must assess whether there is a sufficiently concrete factual basis for making a determination and apply the applicable legal standards of the referenced statute. Proposed paragraph (c) further provides that, upon making a determination regarding whether a particular recipient is exempt from—or subject to a modified requirement under—a specific provision of this part, OCR will communicate that determination to the recipient.

Proposed paragraph (d) provides that if OCR determines that a recipient is entitled to an exemption or modification of the application of certain provisions of this rule based on the application of such laws, that determination does not otherwise limit the application as to any other provision of this part to the recipient.

OCR maintains an important civil rights interest in the proper application of Federal conscience and religious freedom protections. In enforcing Section 1557, OCR is thus committed to complying with RFRA and all other legal requirements. The Department believes that the proposed approach in this section will assist the Department in fulfilling that commitment by providing the opportunity for recipients to raise concerns with the Department, such that the Department can determine whether an exemption or modification of the application of certain provisions is appropriate under the corresponding Federal conscience or religious freedom law. As noted above, the Department also maintains a strong interest in taking a case-by-case approach to such determinations, which will allow it to account for any harm an exemption could have on third parties[595] and, in the context of RFRA, to consider whether the application of any substantial burden on a person's exercise of religion is in furtherance of a compelling interest and is the least restrictive means of advancing that compelling interest.[596]

The Department seeks comment on this approach, including whether such a provision should include additional procedural information, the potential burdens of such a provision on recipients and potential third parties, and additional factors that the Department should take into account when considering the relationship between Federal conscience and religious freedom laws and Section 1557's civil rights protections. We also seek comment on what alternatives, if any, the Department should consider.

Procedures for Health Programs and Activities Conducted by Recipients and State Exchanges (§ 92.303)

Proposed § 92.303 provides for the enforcement procedures related to health programs and activities conducted by recipients and State Exchanges, consistent with former § 92.302 of the 2016 Rule. The 2020 Rule does not include this provision, and instead relies on § 92.5, the general Enforcement Mechanisms section discussed above, which includes a paragraph (b) that notes that the Director has been delegated authority to enforce Section 1557, including the authority to conduct investigations and compliance reviews, make enforcement referrals to the DOJ, and take any other appropriate remedial action the Director deems necessary.

The 2020 Rule does not make sufficiently clear for either covered entities or individuals protected by Section 1557 what procedures will apply in OCR's enforcement of Section 1557. As OCR has clear procedures that apply under Title VI, Title IX, Section 504, and the Age Act, OCR similarly needs to have clear procedures that apply under Section 1557.

Proposed paragraph (a) applies the procedural provisions in the Title VI regulation with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, and disability under Section 1557. Since the effective date of the ACA, OCR has enforced Section 1557 according to the procedural provisions of Title VI. The Title VI procedures have applied to discrimination on the basis of race, color, and national origin for decades, as well as to discrimination on the basis of sex and disability, as the Title VI procedures have been incorporated into the regulations implementing Title IX and Section 504.[597] In the Department's view, therefore, it is logical and appropriate to similarly apply these procedures in enforcement with respect to race, color, national origin, sex, and disability discrimination under Section 1557.

Proposed paragraph (b) applies Age Act procedures to enforce Section 1557 with respect to age discrimination complaints against recipients and State Exchanges. The Age Act has its own set of procedures, and OCR has been applying those procedures in enforcement with respect to age discrimination under Section 1557 from the effective date of the ACA to the present.

Proposed paragraph (c) provides that when a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach a voluntary resolution, find noncompliance with Section 1557 and initiate the appropriate enforcement procedure, found at 45 CFR 80.8. This provision was found at former § 92.302(c) in the 2016 Rule. The 2020 Rule repealed the provision, stating that when a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, absent the need to attempt to effectuate voluntary compliance. The preamble to the 2020 Rule stated that the existing authorities already contain parallel provisions.[598] Yet, the preamble cites a number of provisions that do not support the statement but rather address seeking

[595] *See Cutter* v. *Wilkinson,* 544 U.S. 709, 720 (2005) (in addressing religious accommodation requests, ''courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries'').

[596] *Cf. Gonzales* v. *O Centro Espírita Beneficente União do Vegetal,* 546 U.S. 418, 439 (2006) (''[C]ourts should strike sensible balances, pursuant to a compelling interest test that requires the Government to address *the particular practice at issue.*'') (emphasis added).

[597] 45 CFR 84.61; § 86.71.

[598] 85 FR 37160, 37203 (June 19, 2020).

resolution through voluntary means when there is a failure to comply with the regulation.[599] We believe that the provision we propose at paragraph (c) is helpful in clarifying for recipients and individuals covered by Section 1557 that, should OCR's attempt to effectuate voluntary compliance be unsuccessful, the consequences of failing to provide OCR with information necessary for OCR to determine compliance with the law may include the initiation of the appropriate enforcement procedures, found at 45 CFR 80.8.

Procedures for Health Programs and Activities Administered by the Department (§ 92.304)

Proposed § 92.304 addresses procedures for all claims of discrimination against the Department under Section 1557 or this part. Proposed paragraph (b) makes the existing procedures under the Section 504 federally conducted regulation at 45 CFR 85.61 through 85.62 applicable to all such claims under Section 1557 for all protected bases (*i.e.,* race, color, national origin, sex, age, and disability). This is the only procedure that is currently in place for any discrimination claims against the Department under the laws that OCR enforces. Proposed paragraph (c) requires the Department to provide OCR access to information relevant to determining compliance with Section 1557 or this part, and proposed paragraph (d) prohibits the Department from retaliating against an individual or entity for the purpose of interfering with any right secured by Section 1557 or this part, or because such individual or entity has participated in an investigation, proceeding, or hearing under Section 1557 or this part. This is consistent with the 2016 Rule at former § 92.303.

The 2020 Rule does not include any specific provision for the processing of claims of race, color, national origin, sex, age, or disability discrimination against any covered Departmental program, having rescinded former § 92.303 in its entirety. The other statutes that OCR enforces—Title VI, Title IX, and the Age Act—do not directly apply to the Department. The 2016 Rule adopted the Section 504 procedure for all claims of discrimination against any Departmental health program under Section 1557, a procedure that has been in place for decades, is familiar to the Department and has worked effectively. We believe it is important in this rule to identify the procedure that we will use in enforcing Section 1557 with respect to Departmental health programs and activities and therefore are proposing to do so by reinstating the provision from the 2016 Rule at proposed paragraph (b).

The 2020 Rule also does not include the provision of the 2016 Rule that required the Department to provide OCR access to information necessary to determine compliance with Section 1557. The reason provided was that ''regulations implementing Section 1557's four underlying statutes already contain provisions addressing access to review of covered entities' records of compliance,'' [600] and thus the language in the 2016 Rule to this effect was unnecessary. However, apart from the Section 504 regulation applicable to the Department, none of the other regulations apply to the Department; therefore, provisions under those regulations do not apply to the Department. Consequently, the Department is proposing to reinstate this provision at proposed § 92.304(c).

The 2020 Rule also does not include a prohibition on retaliation that applies to the Department, which was provided at former § 92.303(d). In repealing this provision, the preamble to the 2020 Rule stated that ''regulations implementing Section 1557's four underlying statutes already contain provisions against intimidation and retaliation as appropriate . . . The language in the 2016 Rule to this effect was unnecessary.'' [601] As we have noted, regulations implementing three of the four underlying regulations do not apply to the Department; therefore, we now disagree with the Department's reasoning in 2020.

We are including a retaliation provision at proposed paragraph (d) to make clear that the Department, including Federally-facilitated Exchanges, must not intimidate, threaten, coerce, retaliate, or otherwise discriminate against any individual or entity for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual or entity has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under Section 1557 or this part. The ADA similarly prohibits such retaliation, interference, coercion, and intimidation,[602] and, as discussed *supra* in relation to proposed § 92.3 (relationship to other laws), the ADA and Section 504 are generally understood to impose substantially the same requirements. The Department is thus prohibited from engaging in retaliation, intimidation, coercion, or interferences with rights under Section 504. We are proposing to similarly prohibit the Department from such discrimination under Section 1557. Further, this proposed provision would hold the Department and Federally-facilitated Exchanges to the same standards to which the Department holds all recipients of Federal financial assistance.

IV. Change in Interpretation—Medicare Part B Meets the Definition of Federal Financial Assistance

The Department's longstanding position has been that Medicare Part B funding does not constitute Federal financial assistance for the purpose of Title VI, Title IX, Section 504, the Age Act, and Section 1557.[603] For the reasons discussed below, and after reevaluating the Department's position on Medicare Part B, we are proposing to change that position and treat Medicare Part B funds as Federal financial assistance to the providers and suppliers subsidized by those funds.

To constitute Federal financial assistance, the Federal funds or assistance must confer a benefit or subsidy on the recipient; compensation from the government for services provided to the government is not Federal financial assistance.[604] Further, Congress or the department administering the funds must intend for the assistance to subsidize the entity.[605]

Building on these principles, this rule proposes to define ''Federal financial assistance,'' at proposed § 92.4, in relevant part as ''any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other

[599] *Id.* at n. 253 (discussing 45 CFR 80.7(d) (which requires the Department to seek resolution through informal means where there is a failure to comply with the regulation); § 80.8(c)(1) (note: § 80.8(c) does not include a paragraph (1), but § 80.8(c) requires the Department to seek voluntary compliance and take other steps prior to taking action to terminate Federal financial assistance); § 84.6(b) (stating the right of a recipient to take voluntary action to overcome the effects of conditions that have resulted in limited participation by qualified individuals with disabilities); § 90.49(c) (stating that the provision of special benefits to children or the elderly is generally presumed to be voluntary affirmative action)).

[600] 85 FR 37203.

[601] *Id.*

[602] 42 U.S.C. 12203.

[603] 81 FR 31375, 31383 (May 18, 2016).

[604] *See, e.g., DeVargas* v. *Mason & Hanger-Silas Mason Co., Inc.,* 911 F.2d 1377, 1382 (9th Cir. 1990), *cert. denied,* 498 U.S. 1074 (1991); *Jacobson* v. *Delta Airlines,* 742 F.2d 1202, 1209 (9th Cir. 1984); *Hunter.* v. *D.C.,* 64 F. Supp. 3d 158, 172 (D.D.C. 2020).

[605] *U.S. Dep't of Transport.* v. *Paralyzed Veterans Ass'n,* 477 U.S. 597, 606–07 (1986); *Grove City Coll.* v. *Bell,* 465 U.S. 555, 564 (1984).

arrangement by which the Federal Government provides assistance or otherwise makes assistance available in the form of: (i) Funds; (ii) Services of Federal personnel; or (iii) Real and personal property or any interest in or use of such property, including: (A) Transfers or leases of such property for less than fair market value or for reduced consideration; and (B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.'' This proposed definition is similar to the definition in HHS' regulations implementing the Title VI, Title IX, Section 504, and the Age Act, with the exception of the phrase ''otherwise makes assistance available.'' [606] Similar to the Department's definition of ''recipient'' under the implementing regulations for Title VI, Title IX, Section 504, and the Age Act, the Department proposes to define ''recipient'' as ''any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or indirectly, including any subunit, successor, assignee, or transferee of a recipient, but such term does not include any ultimate beneficiary.'' [607]

In the Department's view, Medicare Part B payments constitute Federal financial assistance and providers subsidized as a result of those payments are recipients. The Department's long-held view that Medicare Part A constitutes Federal financial assistance is instructive.[608] Like Medicare Part A, Medicare Part B is a Department program that provides payment for health services to eligible individuals.[609] Eligible individuals choose to enroll in Medicare Part B and pay a monthly fee for coverage; in exchange, the program covers the services provided by medical providers and suppliers [610] for the services and supplies they provide to these individuals. In addition to fee payments made by beneficiaries, Federal funds are used to subsidize the entities that provide Part B services. The Federal funding benefits Part B beneficiaries by assisting them in paying for necessary health care services; and providers, in turn, receive the benefit of a reliable source of payment for the services provided to eligible patients, at least some of whom may have been unable to afford services otherwise. As in *Grove City College* v. *Bell,* discussed below, the government is assisting providers of services by making available to them a segment of the patient population that either (a) would not have been able to afford any medical services, or (b) would not have been able to afford these specific providers. In these respects, Part B is no different than Part A because Part B is financial assistance to providers that subsidizes their provision of health care to Part B beneficiaries. Further, providers are recipients of these funds because they are entities that operate health programs and activities to whom Federal financial assistance is provided.

Despite these clear similarities, the Department has previously considered Medicare Part A to constitute Federal financial assistance, while analyzing Part B differently. When the Department's Title VI regulation was first published, the Department included an Appendix, titled *Federal Assistance to Which These Regulation Apply.*[611] Although the Appendix is to the Department's Title VI regulation, the Department and courts have relied on it in determining whether Department funds are Federal financial assistance in claims under Title IX, Section 504, and the Age Act, as well.[612] The Appendix contains two lists: ''Assistance Other than Continuing Assistance to States,'' and ''Continuing Assistance to States.'' In the former list, the Department included Medicare Part A, but not Medicare Part B.[613] The omission reflected the Department's position that Medicare Part B did not constitute Federal financial assistance.[614] Many courts have held that Medicare Part A is Federal financial assistance for the purpose of coverage under the Spending Clause civil rights statutes.[615]

In explaining its position that Medicare Part B was not Federal financial assistance in proposing the regulations implementing Section 504, the Department relied on the fact that Medicare Part B is ''provided by way of a contract,'' and thus is a contract of

[606] 45 CFR 80.13(f) (Title VI); § 84.3(h) (Section 504); § 86.2(g) (Title IX); § 91.4 (Age Act).

[607] Proposed § 92.4.

[608] 45 CFR pt. 80 app. A pt. I, No. 121 (Federal Assistance to which these Regulations Apply; Assistance other than continuing assistance to States; Supplementary medical insurance benefits for the aged (Title XVIII, Part A, Social Security Act, 42 U.S.C. 1395c–1395i–2)).

[609] Medicare Part A also pays for hospital coverage and care in skilled nursing facilities. *Parts of Medicare, Medicare.gov, https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare* (last visited June 15, 2022). Medicare Part B provides coverage for outpatient care by physicians and other health care providers, lab tests, home health care, durable medical equipment, and many preventive services. *Id. See also What Medicare Covers, Medicare.gov, https://www.medicare.gov/what-medicare-covers* (last visited June 15, 2022).

[610] We use the term ''providers'' to refer to physician's offices and other entities that provide Part B services, consistent with the use of the term ''provider'' elsewhere in this rule. We acknowledge that this term has a different meaning in the Medicare program.

[611] 45 CFR pt. 80 app. A, pt. I, No. 121.

[612] *See, e.g., Chowdury* v. *Reading Hosp. & Med. Ctr.,* 677 F.2d 317, 318–19 (3d Cir. 1982), *cert. denied,* 463 U.S. 1229 (1983) (Title VI); *Doe* v. *League Sch. of Greater Boston, Inc.,* No. 16–cv–1194, 2017 WL 3594257, at *4 (D. Mass. Aug. 21, 2017) (Title IX).

[613] 45 CFR pt. 80 app. A., pt. I, No. 121.

[614] *See* 81 FR 31375, 31383 (May 18, 2016) (proposing that, ''consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B'' under Section 1557). The Department provided the following explanation in its Section 504 final rule: ''In its May 1976 Notice of Intent, the Department suggested that the arrangement under which individual practitioners, hospitals, and other facilities receive reimbursement for providing services to beneficiaries under Part B of title XVIII of the Social Security Act (Medicare) constitutes a contract of insurance or guaranty and thus falls within the exemption from the regulation. This explanation oversimplified the Department's view of whether Medicare Part B constitutes Federal financial assistance. The Department's position has consistently been that, whether or not Medicare Part B arrangements involve a contract of insurance or guaranty, no Federal financial assistance flows from the Department to the doctor or other practitioner under the program, since Medicare Part B—like other social security programs—is basically a program of payments to direct beneficiaries.'' 45 CFR pt. 84 app. A (Analysis of Final Regulation); 42 FR 22676, 22685 (May 4, 1977).

[615] *See, e.g., U.S.* v. *Baylor Univ. Med. Ctr.,* 736 F.2d 1039, 1042 (5th Cir. 1984), *cert. denied,* 469 U.S. 1189 (1985); *Bernard B.* v. *Blue Cross & Blue Shield,* 528 F. Supp. 125, 132 (S.D.N.Y. 1981), *aff'd,* 679 F.2d 7 (2d Cir. 1982); *Bob Jones Univ.* v. *Johnson,* 396 F. Supp. 597, 603 n. 21 (D.S.C. 1974), *aff'd,* 529 F.2d 514 (4th Cir.1975); *Austin* v *Blue Cross Blue Shield of Ala.,* No. 4:09–cv–1647, 2009 WL 10703738, at *1, n.1 (N.D. Ala. Oct. 16, 2009); *Waris* v. *HCR Manor Care,* No. 07–cv–3344, 2009 WL 330990, at *19 (E.D. Pa. Feb. 10, 2009), *aff'd, on other gr.,* 365 Fed. App'x. 402 (3d Cir. 2021); *Campen* v. *Portland Adventist Med. Ctr.,* No. 3:16–cv–00792; 2016 WL 5853736, at * 4 (D. Or. Sept. 2, 2016), *adopted by* 2016 WL 5858670 (D. Or. Oct. 5, 2016); *Zamora-Quezada* v. *HealthTexas Med. Group. of San Antonio,* 34 F. Supp. 2d 433, 440 (W.D. Tex. 1998); *People by Vacco* v. *Mid Hudson Med. Group, P.C.,* 877 F. Supp. 143, 149–40 (S.D.N.Y. 1995); *Glanz* v *Vernick,* 756 F. Supp. 632, 636 (D. Mass. 1991); *Doe* v. *Centinela Hosp.,* No. 87–cv–2514 PAR, 1988 WL 81776 (C.D. Cal. June 30, 1988); *Bhatt* v. *Uniontown Hosp.,* No. 83–2455, 1986 WL 30681, at *4 (W.D. Pa. Mar. 20, 1986); *U.S.* v. *Univ. Hosp. of the State Univ. of N.Y. at Stony Brook,* 575 F. Supp. 607, 612 (E.D.N.Y. 1983), *aff'd on other gr.,* 729 F.2d 144 (2d Cir. 1984); *U.S.* v *Cabrini Med. Ctr.,* 497 F. Supp. 95, 96 n. 1 (S.D.N.Y. 1980), *rev'd on other gr.,* 639 F.2d 908, 910–11 (2d Cir. 1981); *NAACP* v. *Wilmington Med. Ctr., Inc.,* 453 F. Supp. 280, 329 (D. Del. 1978), *Flora* v. *Moore,* 461 F. Supp. 1104, 1115 (N.D. Miss. 1978). Because many hospitals receive funds under Medicare and Medicaid, many of these cases address both types of funding together. Some of these cases refer specifically to Part A of Medicare in holding that the funds are Federal financial assistance; others refer to Medicare but given that the defendant is a hospital or other facility that Part A funding covers, the funds at issue have been Part A funds.

insurance or guaranty that falls within the exception to ''Federal financial assistance'' in Title VI.[616] In 1977, the Department subsequently clarified, however, that this ''explanation oversimplified the Department's view of whether Medicare Part B constitutes Federal financial assistance.'' [617] In adopting this position in its final rule implementing Section 504, the Department explained that ''its position has consistently been that, whether or not Medicare Part B arrangements involve a contract of insurance or guaranty, no Federal financial assistance flows from the Department to the doctor or other practitioner under the program, since Medicare Part B—like other social security programs—is basically a program of payments to direct beneficiaries.'' [618] Given this clarification, we will focus primarily here on the Department's 1977 rationale that no Federal financial assistance flows from the Department to a provider under the program.

The Department's 1977 rationale regarding the payment to beneficiaries no longer reflects how Medicare Part B operates. When the Medicare Part B program was first enacted in 1965, program beneficiaries generally paid for services out of pocket and received partial reimbursement from the program. That is no longer the most common method by which providers receive funds. The Medicare and Medicaid Act (the ''Medicare Act'') currently allows physicians and many other Part B providers and suppliers to ''accept assignment'' for Medicare Part B claims.[619] Providers thereby accept Medicare's approved amount for a service and can only charge a beneficiary co-insurance and a deductible.[620] Providers bill the Medicare program directly for services they provide to Part B program beneficiaries and are paid directly by the Department.[621]

Significantly, at the present time, approximately two-thirds of providers enrolled in the Medicare Part B program are ''participating providers,'' [622] *i.e.,* providers that bill and are paid by the Medicare program. Thus, the Department's primary historical rationale for its position that Medicare Part B was not Federal financial assistance does not reflect the current operation of the program for the majority of providers participating in the program. Those providers have become direct recipients of Federal financial assistance. This significant change in facts provides ample support for the Department's change of interpretation as applied to those providers.[623]

Providers commonly known as ''non-participating providers'' also provide services to Medicare beneficiaries, but they do not agree to accept Medicare's approved amount as full payment, and can charge up to 15 percent more than Medicare's approved amount.[624] They also receive a lower payment rate through the program.[625] Non-participating providers must enroll in the Part B program for their services to be covered by the program, but do not receive direct payment from the Part B program.[626] Thus, whereas they are referred to as ''non-participating'' because they do not receive direct Medicare assignment and are not subject to the usual participating provider fee limitations like participating providers, non-participating providers do participate in the Part B program overall, and enroll in the program so that the services they provide to Part B beneficiaries will be subsidized by the program. (In contrast, providers referred to as ''opt-out providers'' opt out of Medicare Part B entirely, and Medicare does not pay for the services these providers provide to Part B beneficiaries, either directly to providers themselves, or by reimbursing Part B beneficiaries after the fact for these services.) [627]

Given this relationship of non-participating providers to the Medicare Part B program, the Department believes that non-participating providers are also recipients of Federal financial assistance under the principles set forth by the Supreme Court in *Grove City College* v. *Bell,* where the Court held that Federal assistance loans provided to students to cover education-related expenses is Federal financial assistance to educational institutions under Title IX.[628] The Court explained that ''[n]othing . . . [] suggests that Congress elevated form over substance by making the application of the nondiscrimination principle dependent on the manner in which a program or activity receives Federal assistance. There is no basis in the statute for the view that only institutions that themselves apply for Federal aid or receive checks directly from the Federal Government are subject to regulation.'' [629]

Critically, the Court noted that the Federal financial assistance in question ''was structured to ensure that it effectively supplements the College's own financial aid program.'' [630] In doing so, it rejected the argument that student loans were akin to general assistance programs such as ''food stamps, Social Security benefits, welfare payments, and other forms of general-purpose governmental assistance to low-income families.'' [631] Among the reasons the Court cited for this rejection were the fact that ''general assistance programs, unlike student aid programs, were not designed to assist colleges and universities'' and that ''educational institutions have no control over, and indeed perhaps no knowledge of, whether they ultimately receive Federal funds made available to individuals under general assistance programs [like Social Security], but they remain free to opt out of Federal student assistance programs.'' [632] Entities such as non-participating providers are aware of the flow of Federal financial assistance to them and are permitted to opt out.

In the Department's view, the rationale set forth in *Grove City College* counsels in favor of considering non-participating providers under Medicare Part B to be indirect recipients of Federal financial assistance. Part B funds, like the Federal student aid provided to students at issue in *Grove City College,* are ''designed'' to effectively subsidize health care providers and suppliers for the health services and supplies they provide to program beneficiaries. Program beneficiaries who see a non-participating provider receive a Part B payment from the program for one reason only: they have received health services or supplies from a provider that has enrolled in the Part B program and paid for the service out of pocket. The amount that the provider may charge is controlled by the terms of the provider's

[616] 41 FR 20296, 20298 (May 17, 1976) (discussing 42 U.S.C. 2000d–1, d–4).

[617] 42 FR 22685.

[618] *Id.;* 41 FR 20298.

[619] 42 U.S.C. 1395u(h)–(i).

[620] *Lower Costs with Assignment, Medicare.gov, https://www.medicare.gov/your-medicare-costs/part-a-costs/lower-costs-with-assignment* (last visited June 15, 2022).

[621] *Id.*

[622] Medicare Provider Enrollment Chain and Ownership System (PECOS), *https://pecos.cms.hhs.gov/pecos/login.do#headingLv1* (last visited June 15, 2022).

[623] *See Nat'l Cable & Telecomms. Ass'n* v. *Brand X internet Servs.,* 545 U.S. 967, 981 (2005) (''[a]n initial agency interpretation is not instantly carved in stone. On the contrary, the agency . . . must consider varying interpretations and the wisdom of its policy on a continuing basis, for example, in response to changed factual circumstances . . .'').

[624] 42 U.S.C. 1395w–4(g)(1); *Lower Costs with Assignment, supra* note 620.

[625] *Lower Costs with Assignment, supra* note 620.

[626] 42 CFR 424.510.

[627] *Lower Costs with Assignment, supra* note 620.

[628] *Grove City Coll.* v. *Bell,* 465 U.S. 555, 565 (1984).

[629] *Id.* at 564.

[630] *Id.* at 565.

[631] *Id.* at n.13

[632] *Id.*

enrollment agreement in Medicare Part B. Accordingly, even though a non-participating provider does not accept assignment, it remains a willing participant in the Medicare Part B program and it agrees to treat patients receiving Medicare Part B with the awareness that its services that will be subsidized by the Department. In contrast to general assistance programs, and similar to the student aid program at issue in *Grove City College,* non-participating providers thus have knowledge and control of whether they receive Federal funds and their participation status, and remain free to opt out.[633] Further, Title VI, Section 504, Title IX, the Age Act, and this proposed rule all require entities to sign an assurance of compliance with these laws as a condition of receiving Federal funds.[634] Thus both participating and non-participating providers will have a choice as to whether to accept the funds and comply with these civil rights laws or decline the funds.

Accordingly, the Department's principal 1977 rationale regarding the flow of Federal assistance can no longer justify excluding Medicare Part B payments from the definition of Federal financial assistance. Participating providers are the direct recipients of Federal financial assistance; and non-participating providers are the indirect recipients of such assistance.

A second rationale that the Department has mentioned as potential support for its past position that Medicare Part B is not Federal financial assistance is that Medicare Part B is a ''contract of insurance or guaranty.'' [635] The Title VI statute [636] and regulations, and Section 504, Title IX, and Age Act regulations [637] exclude a contract of insurance from the definition of ''Federal financial assistance.'' Significantly, after initially relying on this rationale, the Department clarified that its position did not depend on this rationale.[638] Moreover, this prior rationale does not provide a strong basis for interpreting Medicare Part B as something other than Federal financial assistance.

First, with respect to Section 1557 in particular, Congress made clear in the text of the statute that a ''contract of insurance'' *can* constitute Federal financial assistance, expressly declining to include the exception from Title VI.[639] Thus, whatever the meaning of that exception might be in Title VI, and in the Title IX, Section 504, and Age Act regulations, it does not apply to Section 1557.

Second, the Department now is of the view that Medicare Part B funding is not covered by that Title VI exception, because it is not a ''contract of insurance or guaranty.'' It is instructive, in this regard, to consider how the Department has analyzed Medicare Part A with respect to the question of what constitutes Federal financial assistance. Medicare Part A and Part B are fundamentally similar in many respects. Both are Federal programs providing health-related coverage to eligible individuals. In both, providers agree to meet conditions of participation or coverage in exchange for receiving payments for their services to eligible enrolled individuals. In both, payments come from a Federal trust fund. In both, the services covered, fees paid, and other aspects of the program are governed by a variety of statutes and regulations. That participation in Part B is voluntary for eligible individuals does not make Part B funds a ''contract of insurance or guaranty,'' particularly since some individuals who do not qualify for ''premium-free'' Part A coverage can ''buy-in'' to Medicare Part A.[640] Part A buy-in has been a feature of Medicare since 1972, though the statute has subsequently been amended to expand eligibility for this option.[641] Both Parts contain the word ''insurance'' in their Titles; [642] yet Medicare Part A has always been considered Federal financial assistance by the Department, notwithstanding this denomination. Thus, the use of this term in Part B has no more significance than it does in Part A. In both programs, insurance companies serve as Medicare Administrative Contractors, processing claims and paying providers [643] as agents of the Department, not as insurers of individuals. We note as well that most of the funding for the Part B fund comes from Federal and State tax revenue and interest on investments, not ''premium'' payments.[644]

The Department seeks comment on the impact that this proposed change may have on recipients subsidized only by Medicare Part B funds and no other sources of Federal financial assistance from the Department. We also seek comment on the time that should be allowed for recipients of Part B funds to come into compliance with the applicable statutes and their implementing regulations and what resources the Department can provide to assist newly covered entities in coming into compliance.

V. CMS Amendments

The 2020 Rule amended ten provisions in CMS regulations, at least some of which cover entities that are also subject to Section 1557, to delete language that prohibited discrimination on the basis of sexual orientation and gender identity.[645] These provisions included regulations governing

[633] *Id.*

[634] 45 CFR 80.4 (Title VI); § 84.5 (Section 504); § 86.4 (Title IX); § 91.33 (Age Act); proposed § 92.5.

[635] 41 FR 20296, 20298 (May 17, 1976).

[636] 42 U.S.C. 2000d *et seq.* The legislative history of Title VI indicates that the ''contract of insurance or guaranty'' exclusion was added to the bills that became Title VI to address the concern of some members of Congress that without the exclusion, federally insured banks providing housing mortgages would be covered by Title VI and be prohibited from denying mortgages based on ''the choice of a neighbor,'' *i.e.,* engaging in redlining, a practice now prohibited by the Federal Fair Housing Act. 110 Cong. Rec. 1345–6 (Statement of Sen. Pastore); 110 Cong. Rec. 1497–1500 (colloquy between Rep. Cramer, and Willard W. Wirtz, Secretary of Labor); 110 Cong. Rec. 1519 (Statement of Rep. Heller); 110 Cong. Rec. 13377–78 (June 10, 1964) (Statement of Sen. Long),110 Cong. Rec. 13435 (June 10, 1964) (Statement of Sen. Humphrey). 110 Cong. Rec. 13454–6 (Statement of Sen. Pastore); 110 Cong. Rec. 13435 (June 10, 1964) (Statement of Sen. Humphrey). When Medicare was being enacted, some indications in the legislative history suggest that Congress assumed that Title VI would apply to it. *See, e.g.,* 111 Cong. Rec. 15813 (July 7, 1965) (Statement of Sen. Hart).

[637] 45 CFR 80.13(f) (Title VI); § 84.3(h) (Section 504); § 86.2(g) (Title IX); § 91.4 (Age Act).

[638] 42 FR 22685.

[639] 42 U.S.C. 18116(a).

[640] *Part A Costs, Medicare.gov, https://www.medicare.gov/your-medicare-costs/part-a-costs* (last visited June 15, 2022).

[641] Public Law 92–603, 202, 86 Stat. 1329 (Oct. 30, 1972), *as amended by,* The Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, 6013, 103 Stat. 2106 (Dec. 19, 1989).

[642] 42 U.S.C. ch. 7, subch. XVIII, pt. A (Hospital Insurance Benefits for Aged and Disabled); 42 U.S.C. ch. 7, subch. XVIII, pt. B (Supplementary Insurance Benefits for Aged and Disabled).

[643] 42 U.S.C. 1395kk–1; *Medicare Administrative Contractors,* Ctrs. for Medicare & Medicaid Servs., *https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MedicareAdministrativeContractors* (last visited June 15, 2022).

[644] Tax Policy Ctr., Tax Policy Center Briefing Book: Key Elements of the U.S. Tax System, *https://www.taxpolicycenter.org/briefing-book/what-medicare-trust-fund-and-how-it-financed* (last visited June 15, 2022) (indicating SMI trust fund received over 70% of its 2017 year assets from general revenue, including individual income taxes, corporate taxes, and excise taxes).

[645] *See* 85 FR 37160, 37162 (June 19, 2020) (the provisions that were amended included: Medicaid and CHIP (42 CFR 438.3(d)(4), § 438.206(c)(2), § 440.262); PACE (42 CFR 460.98(b)(3), § 460.112(a)); issuers offering coverage in the group and individual markets (45 CFR 147.104(e)); Exchange-related programs (45 CFR 155.120(c)(1)(ii), § 155.220(j)(2)(i), § 156.200(e), § 156.1230(b)(2)). 45 CFR 147.104 applies not only to issuers subject to Section 1557, but to all health insurance issuers offering non-grandfathered individual, small group, and large group health insurance, and § 156.125(b) applies not only to issuers subject to Section 1557, but to all health insurance issuers offering non-grandfathered individual and small group health insurance.

Medicaid and CHIP;[646] PACE;[647] health insurance issuers including issuers providing essential health benefits (EHB) and issuers of qualified health plans (QHPs), and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; and agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees.[648] The 2020 Rule stated that in light of the overarching applicability of Section 1557 to these programs and entities, the Department was making these amendments to ensure greater consistency in civil rights enforcement across the Department's different programs.[649] See *supra* section II.B. for additional detail.

The Department is committed to ensuring that all persons should be able to access health care without being subjected to sex discrimination, and that all persons should receive equal treatment under the law, no matter their gender identity or sexual orientation. Accordingly, in this proposed rule, the Department proposes to amend these CMS regulations[650] so that they again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. In addition, the Department proposes to amend a regulation applying these protections in CHIP to also apply to Medicaid fee-for-service programs and managed care programs. These proposals are consistent with those elsewhere in this proposed rule and would ensure that sexual orientation and gender identity are added and promote consistency across HHS programs of policies and requirements that prohibit discrimination based on sexual orientation or gender identity. In the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023'' published in the **Federal Register** on January 5, 2022 (2023 Payment Notice proposed rule),[651] HHS proposed similar amendments to some of those same regulations applicable to Exchanges, QHPs, and certain issuers to prohibit discrimination based on sexual orientation and gender identity.[652] These provisions were not finalized in the Final Rule published on May 6, 2022.[653] Commenters that provided comments on the 2023 Payment Notice proposed rule should not submit duplicative comments to this proposed rule as the Department will consider all comments previously submitted regarding these proposals in issuing its final rule.

Prohibiting sex discrimination based on sexual orientation and gender identity can lead to improved health outcomes for members of the LGBTQI+ community. Without such protection, individuals will likely continue facing barriers to accessing medically necessary health care. For example, without protection from discrimination, transgender individuals may face barriers or be denied clinically appropriate gender-affirming care.

On June 15, 2020, the U.S. Supreme Court held that Title VII's prohibition on employment discrimination based on sex encompasses discrimination based on sexual orientation and gender identity.[654] The *Bostock* majority concluded that the plain meaning of ''because of sex'' in Title VII necessarily included discrimination because of sexual orientation and gender identity.[655] Subsequently, DOJ's Civil Rights Division issued a memorandum[656] concluding that the Supreme Court's reasoning in *Bostock* applies to Title IX. As made clear by the ACA, Section 1557 prohibits discrimination ''on the ground prohibited under . . . Title IX.''[657]

Consistent with *Bostock,* HHS OCR issued its Bostock Notification, interpreting Section 1557's prohibition on discrimination on the basis of sex to include discrimination on the basis of sexual orientation and gender identity. Based on this and the statutory authorities identified below, the Department also relies on Section 1557 as authority for the proposed amendments to 45 CFR 155.120, 155.220, 156.200, and 156.1230 as well as 42 CFR 438.3(d)(4), 42 CFR 438.206(c)(2), and 42 CFR 440.262 in this proposed rule. CMS is also proposing a parallel amendment to 45 CFR 147.104 that would prohibit discrimination on the basis of sex (including on the basis of sexual orientation or gender identity) consistent with the Section 1557 implementing regulations proposed in this rule but is relying on the separate authorities identified later in this discussion. We are also including a discussion at 45 CFR 156.125 that clarifies how the proposed change to 45 CFR 156.200 would impact the nondiscrimination requirements for plans providing EHB such that plans subject to EHB requirements would be prohibited from discriminating on the basis of sex (including sexual orientation or gender identity) relying on separate authorities identified below. Subpart B of this NPRM discusses the Section 1557's prohibition on discrimination on the basis of sex (including pregnancy, sex characteristics, sexual orientation, and gender identity). This portion of the preamble focuses on the CMS freestanding, independent provisions that have long provided for nondiscrimination on the basis of sex in its programs and services. While the Section 1557 NPRM proposes to include sex stereotypes, sex characteristics, pregnancy or related conditions, sexual orientation, and gender identity as enumerated forms of sex discrimination, CMS limits the explicit mention to gender identity and sexual orientation, while understanding that discrimination on the basis of sex stereotypes, sex characteristics, and pregnancy or related conditions is prohibited sex discrimination. We seek comment on this approach for all of the CMS provisions addressed in this section.

A. Medicaid and Children's Health Insurance Program (CHIP)

In the Medicaid and CHIP managed care final rule published in the **Federal Register** on May 6, 2016,[658] CMS explicitly included prohibitions on discrimination based on sexual orientation or gender identity. In that rulemaking, CMS explained that adopting protections against discrimination on these bases was necessary to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19)

[646] The 2020 Rule, at 85 FR 37221, removed references to sexual orientation and gender identity as a prohibited basis of discrimination from 42 CFR 438.3(d)(4), § 438.206(c)(2), and § 440.262.

[647] The 2020 Rule, at 85 FR 37220–21, removed references to sexual orientation from 42 CFR 460.98(b)(3) and § 460.112(a). However due to a publishing error, the text of § 460.112(a) still states that PACE participants have the right not to be discriminated against on the basis of sexual orientation.

[648] The 2020 Rule, at 85 FR 37221, removed references to sexual orientation and gender identity as a prohibited basis of discrimination from 45 CFR 147.104(e), § 155.120(c)(1)(ii), § 155.220(j)(2)(i), § 156.200(e), and § 156.1230(b)(2).

[649] 85 FR 37162.

[650] See 85 FR 37162 (the provisions that were amended included: Medicaid and CHIP (42 CFR 438.3(d)(4), § 438.206(c)(2), § 440.262); PACE (42 CFR 460.98(b)(3), § 460.112(a)); issuers offering coverage in the group and individual markets (45 CFR 147.104(e)); Exchange-related programs (45 CFR 155.120(c)(1)(ii), § 155.220(j)(2)(i), § 156.200(e), § 156.1230(b)(2)).

[651] 87 FR 584 (Jan. 5, 2022).

[652] 45 CFR 147.104(e); § 155.120(c)(1)(ii); § 155.220(j)(2)(i); § 156.200(e); § 156.1230(b)(2).

[653] 87 FR 27208, 27209 (May 6, 2022).

[654] *Bostock* v. *Clayton Cnty.,* 140 S. Ct. 1731 (2020).

[655] *Id.* at 1753–54.

[656] Karlan Memo, *supra* note 46.

[657] 42 U.S.C. 18116(a).

[658] 81 FR 27498 (May 6, 2016).

of the Social Security Act (''the SSA'') and relied on authority under section 1902(a)(4) of the SSA to adopt regulatory antidiscrimination protections and obligations for managed care plans.[659] We amended 42 CFR 438.3(d)(4), which prohibits enrollment discrimination in contracts with managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case managers, and primary care case management entities, as well as 42 CFR 438.206(c)(2), which, as amended, required each managed care organization, prepaid inpatient health plan, and prepaid ambulatory health plan to participate in a ''State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, . . . regardless of gender, sexual orientation or gender identity.'' We also explained that the obligation for the state plan to promote access and delivery of services without discrimination was necessary to assure that care and services were provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the SSA.[660] Therefore, in the Medicaid and CHIP managed care 2016 final rule, we created a new provision entitled ''Access and cultural considerations'' at 42 CFR 440.262, requiring states to 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 gender, sexual orientation or gender identity.'' In addition, 42 CFR 438.3(f) (which is also applicable to CHIP managed care entities per § 457.1201(f)), requires compliance with all applicable Federal and State laws and regulations, including Section 1557. The antidiscrimination provision in § 438.3(d)(4) also applied to CHIP managed care entities under § 457.1201(d); those CHIP managed care regulations apply the terms of the Medicaid managed care regulations through existing cross-references. As explained in the Medicaid and CHIP managed care 2016 final rule, CMS believes it is appropriate to align the requirements for managed care programs in the Medicaid and CHIP contexts, including with regard to beneficiary protections and access to services.[661]

Due to an oversight, the Medicaid and CHIP managed care 2016 final rule did not apply the provisions requiring nondiscrimination as described in 42 CFR 440.262 to fee-for-service CHIP programs. In the Department's view, providing access to services in a non-discriminatory manner is in the best interest of all CHIP beneficiaries. CMS therefore now proposes to rectify that omission by incorporating 42 CFR 440.262 into CHIP regulations through a cross-reference at 42 CFR 457.495(e). Taken together, these protections further the purpose of CHIP to provide child health assistance in an effective and efficient manner that is consistent with section 2101(a) of the SSA.

CMS now proposes, based on Section 1557 as discussed previously, and its separate statutory authority under sections 1902(a)(4) of the SSA (codified at 42 U.S.C. 1396a(a)(4)) and 2101(a) of the SSA (codified at 42 U.S.C. 1397aa(a)), to amend 42 CFR 438.3(d)(4), 42 CFR 438.206(c)(2), and 42 CFR 440.262 to again prohibit Medicaid and CHIP managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case managers, and primary care case management entities in managed care programs from discriminating on the basis of sexual orientation and gender identity, and to require managed care plans and State fee-for-service Medicaid and CHIP programs 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 gender, sexual orientation or gender identity. As noted above, the managed care contracting and service delivery provisions would also apply to CHIP managed care entities based on existing regulations, creating an alignment in the Medicaid and CHIP managed care requirements.

As HHS noted in its 2016 Medicaid CHIP managed care final rule,[662] CMS possesses statutory authority to amend 42 CFR 438.3(d)(4), 42 CFR 438.206(c)(2), and 42 CFR 440.262 under section 1902(a)(4) of the SSA, which authorizes the Secretary to adopt methods of administration necessary for the proper and efficient operation of the Medicaid state plan; section 1902(a)(19) of the SSA (codified at 42 U.S.C. 1396a(a)(19)), which requires the Medicaid state plan to provide safeguards as necessary to assure that covered services are provided in a manner consistent with the best interests of the recipients; and section 2101(a) of the SSA (codified at 42 U.S.C. 1397aa(a)), which permits provision of funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. CMS interprets section 1902(a)(19) of the SSA as prohibiting discrimination in the delivery of services because such discrimination is inconsistent with the best interests of the Medicaid beneficiaries who are eligible for and receive services. CMS interprets sections 1902(a)(4) and 2101(a) of the SSA as authorizing CMS to adopt regulations prohibiting discrimination on the basis of gender identity or sexual orientation because such prohibitions on discrimination are necessary for the proper and efficient operation of a state plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner. Adopting regulations to ensure that eligible beneficiaries receive services under these programs is consistent with the purpose of the Medicaid and CHIP programs to furnish and expand access to medical assistance. The proposed amendments to 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, and 457.495(e) would explicitly prohibit discrimination on the basis of sexual orientation and gender identity in addition to the existing prohibitions imposed on Medicaid and CHIP under Section 1557. Importantly, adopting a broader interpretation of what is necessary and appropriate to ensure proper and efficient Medicaid and CHIP programs and to ensure services are delivered in a manner that is in the best interest of the beneficiary is warranted in light of the existing trends in health care discrimination [663] and to better address barriers to health equity. Section II.D. of this NPRM includes an extensive discussion of LGBTQI+ health disparities. These CMS conforming amendments, in addition to the broad prohibition on discrimination required under Section 1557, allow CMS to ensure that its programs and services are operated without discrimination and would help address those disparities. While we are restoring 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, and adding 457.495(e), as part of using our longstanding program authority, Section 1557 requires nondiscrimination in these programs and services.

[659] 80 FR 31097, 31147–48 (June 1, 2015); 81 FR 27538–39, 27666.

[660] 81 FR 27666.

[661] 80 FR 31169–71, 31173; 81 FR 27757–58, 27765.

[662] 81 FR 27498.

[663] Thu T. Nguyen et al., *Trends for Reported Discrimination in Health Care in a National Sample of Older Adults with Chronic Conditions,* 33 J. Gen. Intern. Med. 291 (2018), *https://doi.org/10.1007/s11606-017-4209-5.*

Section 1557 prohibits discrimination on the basis of sex, importantly including sexual orientation and gender identity. CMS is proposing to amend 42 CFR 440.262 to restore the explicit prohibition against discrimination in the delivery of services on the basis of sexual orientation and gender identity. We also propose to replace ''gender'' with ''sex'' and add ''(including sexual orientation and gender identity)'' for consistency with the proposals elsewhere in this proposed rule, to ensure that sexual orientation and gender identity are added, and to promote consistency across HHS programs. As adopted in 2016, the regulation at 42 CFR 440.262 was described by CMS as an obligation for the state Medicaid plan to promote access and delivery of services without discrimination [664] and the proposal here reiterates the meaning and scope for this regulation. By reinstating the explicit references to sexual orientation and gender identity as forms of sex discrimination, this proposal would amend 42 CFR 440.262 to protect individuals from discrimination on those bases in the same way that discrimination on the basis of limited English proficiency, disabilities, and cultural and ethnic backgrounds is prohibited. We also propose to change ''unique needs'' in 42 CFR 440.262 to ''individualized needs'' to more accurately reflect Medicaid's goal of providing person-centered care. As adopted in 2016, the regulation at 42 CFR 438.206(c)(2) required Medicaid managed care plans to participate in the State efforts to promote the delivery of services in a manner required by 42 CFR 440.262,[665] so CMS is proposing to amend 42 CFR 438.206(c)(2) to reinstate the references to sexual orientation and gender identity to align the Medicaid managed care regulation with the proposal to amend 42 C.F.R 440.262. Similarly, CMS is proposing to reinstate references to sexual orientation and gender identity in the Medicaid managed care regulation at 42 CFR 438.3(d)(4) that prohibits Medicaid managed care plans from discriminating against individuals eligible to enroll and from using any policy or practice that has the effect of discriminating on the basis of listed characteristics, which currently include race, color, national origin, sex, or disability. For consistency with the proposals elsewhere in this proposed rule to ensure that sexual orientation and gender identity are added and promote consistency across HHS programs for how protections against discrimination on the basis of sexual orientation or gender identify are reflected in regulation, we propose to revise the term ''sex'' in the current regulation text to ''sex (including sexual orientation and gender identity)'' at 42 CFR 438.206(c)(2) and 42 CFR 438.3(d)(4).

CMS also proposes to add a similar nondiscrimination provision for CHIP, to apply to fee-for-service and managed care delivery systems, by incorporating 42 CFR 440.262 into CHIP regulations through a cross-reference at 42 CFR 457.495(e). Because of existing cross-references in 42 CFR 457.1201(d) and 457.1230(a), the amendments to the Medicaid managed care regulations at 42 CFR 438.3(d)(4) and 438.206(c)(2) would also apply to CHIP managed care entities.

Finally, the Department proposes that if any of the provisions at CFR 457.495(e), 42 CFR 440.262, 42 CFR 438.206(c)(2) and 42 CFR 438.3(d)(4) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from its respective sections and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in these CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including RFRA and all other applicable legal requirements.

B. Programs of All-Inclusive Care for the Elderly (PACE)

CMS issued an interim final rule implementing the Programs of All-Inclusive Care for the Elderly (PACE) on November 24, 1999.[666] In response to comments received on the November 24, 1999 interim final rule, in a December 8, 2006 Final Rule,[667] CMS added references to ''sexual orientation'' to several PACE regulations intended to prevent discrimination against PACE participants, consistent with CMS' authority under sections 1894(f) and 1934(f) of the SSA. Specifically, CMS amended 42 CFR 460.98(b)(3) to prohibit PACE organizations from discriminating against any participant in the delivery of required PACE services based on sexual orientation, among other bases. Similarly, CMS modified § 460.112(a) to affirmatively state that each PACE participant has the right not to be discriminated against in the delivery of required PACE services based on sexual orientation, among other bases.

Congress authorized PACE under both Medicare and Medicaid, in sections 1894 and 1934 of the SSA, codified at 42 U.S.C. 1395eee and 42 U.S.C. 1396u–4, respectively. For a description of the relevant legislative history, we direct readers to the December 8, 2006 Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions final rule.[668] Sections 1894(f) and 1934(f) of the SSA set forth the requirements for issuing regulations to carry out sections 1894 and 1934. Sections 1894(f)(2) and (3) and 1934(f)(2) and (3) include certain provisions relating to beneficiary and program protections under PACE. Sections 1894(f)(4) and 1934(f)(4) however, provide in identical terms that ''[n]othing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program under this section that are in addition to those otherwise provided under paragraphs (2) and (3).'' This authority allows CMS to implement regulations to provide additional protections to ensure the health and safety of PACE participants in addition to those specified in sections 1894(f)(2) and (3) and 1934(f)(2) and (3).

PACE participants are some of CMS's most vulnerable and frail beneficiaries, with the vast majority dually eligible for both Medicare and Medicaid. To be eligible to enroll in a PACE program an individual must be determined to need the level of care required under the state Medicaid plan for coverage of nursing facility services.[669] One of the purposes of the PACE program is to enable PACE participants to live in the community with the support of PACE services as long as medically and socially feasible, instead of residing in a nursing facility or other institutional setting.[670] While PACE participants receive care in a wide range of settings, including the PACE center, the home, and inpatient facilities, given the general characteristics of the PACE population, PACE organization staff interact with PACE participants in much the same way that nursing facility staff work with long-term care residents who are not PACE participants. Given the role of the PACE organization and the frequent interactions between PACE staff and PACE participants, the need to ensure

[664] 81 FR 27666.

[665] *Id.*

[666] 64 FR 66234 (Nov. 24, 1999).

[667] 71 FR 71244 (Dec. 8, 2006).

[668] *Id.*

[669] 42 CFR 460.150(b)(2).

[670] *Id.* at § 460.4(b)(3).

discrimination does not occur is even greater.

As addressed above, CMS now proposes, using its authority under section 1557 of the ACA and its authorities under sections 1894(f)(4) and 1934(f)(4) of the SSA, to amend PACE regulations at 42 CFR 460.98(b)(3) and 460.112(a) to explicitly prohibit discrimination on the basis of sexual orientation or gender identity.

Revised § 460.98(b)(3) would state that PACE organizations may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sexual orientation and gender identity), age, mental or physical disability, or source of payment. Similarly, we are proposing to revise 42 CFR 460.112(a) to add references to ''sexual orientation'' and ''gender identity'' to establish a right for each PACE participant not to be discriminated against in the delivery of required PACE services on the basis of sexual orientation or gender identity. Revised § 460.112(a) will provide in relevant part that each PACE participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sexual orientation and gender identity), age, mental or physical disability, or source of payment.

In addition, in the proposed rule, ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023'' published in the **Federal Register** on January 5, 2022 (2023 Payment Notice proposed rule),[671] HHS proposed to amend certain regulations applicable to Exchanges, qualified health plans (QHPs), and certain issuers to prohibit discrimination based on sexual orientation and gender identity.[672] That proposed rule discussed that LGBTQI+ individuals face pervasive health and health care disparities,[673] and are at higher risk for many concomitant conditions and that overall, LGBTQI+ people report being in poorer health than non-LGBTQI+ individuals.[674] The 2015 report, *LGBT Older Adults in Long-Term Care Facilities,* found that elders in this community are more likely to be single, childless, estranged from their biological family, and reliant on families of choice, such as friends and other loved ones, for informal support.[675] Available research indicates that nursing home staff may be unfamiliar with the challenges and stigma faced by the LGBTQI community.[676] Many of these nursing facilities studied also failed to have care plans in place that ensured the safety of their LGBTQ residents and lacked a meaningful appreciation for their specific history.[677] One survey of nursing home social workers suggested that more than half of nursing home staff were ''either intolerant of homosexuality . . . or openly negative and condemnatory.'' [678] Research suggests that nursing home staff may also fail to provide equal care to the LGBTQI+ community. For instance, research has shown that nursing home staff sometimes fail to provide basic care such as bathing, toileting, and feeding for LGBTQI+ residents at higher rates than for residents who are not, because of staff refusal to touch LGBTQI+ residents.[679]

As described earlier in this section, the functions filled by PACE organization staff are often similar to those filled by nursing home staff (*e.g.,* bathing, toileting, and feeding). Since the functions are similar, PACE organizations would typically employ people with the same training and education as nursing home staff. Therefore, it is reasonable to assume that nursing home staff and PACE staff might treat individuals in much the same way. In fact, since PACE staff are generally required to have one year of experience working with the frail or elderly population,[680] which is similar to the population with which nursing home staff work, it is also reasonable to assume that nursing home staff might transfer to a PACE organization. As a result, we believe that PACE participants, regardless of the care setting, may encounter the same or similar issues as nursing home residents when receiving services from the PACE organization.

As explained earlier in this section of this proposed rule, research on nursing home care indicates that LGBTQI+ individuals often do not receive the health care needed to maintain and improve their overall health status. Since PACE participants have similarities to nursing home residents, we believe many of the same nursing home concerns might affect the provision of the benefits PACE organizations are required to provide under § 460.92(a). As discussed *supra* section II.B., LGBTQI+ individuals experience high rates of health disparities.

The PACE benefit package for all participants, regardless of the source of payment, must include all Medicare-covered services; all Medicaid-covered services, as specified in the State's approved Medicaid plan; and other services determined necessary by the participant's interdisciplinary team (IDT) to improve and maintain the participant's overall health status.[681] Decisions by the IDT to provide or deny services must be based on an evaluation of the participant's current medical, physical, emotional and social needs and current clinical practice guidelines and professional standards of care applicable to the particular service.[682] Furthermore, the IDT must perform an initial in-person comprehensive assessment of each participant.[683] This includes evaluating the physical and cognitive function and ability of each participant, the participant's and caregiver's preferences for care, socialization and availability of family support, current health status and treatment needs, and other factors. These requirements are intended to ensure that the IDT makes decisions based on the unique needs of each

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[671] 87 FR 584 (Jan. 5, 2022).

[672] As discussed *infra* section V.C., the Department did not finalize these provisions in the Payment Notice final rule (87 FR 27208, 27209 (May 6, 2022)) because this proposed rule addressing Section 1557 also would address issues related to prohibited discrimination based on sex. Therefore, the Department determined that it would be most prudent to address the nondiscrimination proposals related to sexual orientation and gender identity in this Section 1557 proposed rule to ensure consistency across the policies and requirements applicable to entities subject to Section 1557.

[673] *See, e.g., Lesbian, Gay, Bisexual, and Transgender Health, Healthy People 2020, HealthyPeople.gov, https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health* (last visited June 15, 2022); Hudaisa Hafeez et al., *Healthcare Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review,* 9 Cureus e1184 (2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215/;* Karen I. Fredriksen-Goldsen et al., *Health Disparities Among Lesbian, Gay, and Bisexual Older Adults: Results from a Population-Based Study,* 103 A.m. J. Pub. Health 1802 (2013), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3770805/;* Billy A. Caceres et al., *A Systematic Review of Cardiovascular Disease in Sexual Minorities,* 107 A.m. J. Public Health e13–e21 (2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5343694/.*

[674] Daniel, *supra* note 119.

[675] Nat'l Senior Citizens Law Center et al., LGBT Older Adults in Long-Term Care Facilities (last updated 2015), *https://www.lgbtagingcenter.org/resources/pdfs/NSCLC_LGBT_report.pdf.*

[676] Alan Moses, *A Second ''Closet'' for Some LGBTQ Seniors Entering Nursing Homes,* U.S. News (Aug. 10, 2021), *https://www.usnews.com/news/health-news/articles/2021-08-10/a-second-closet-for-some-lgbtq-seniors-entering-nursing-homes.*

[677] *Id.*

[678] David Henry Wolfenson, *The Risks to LGBT Elders in Nursing Homes and Assisted Living Facilities and Possible Solutions,* 26 Tul. J. L. & Sexuality 123 (2017), *https://journals.tulane.edu/tjls/article/view/3020/2812.*

[679] *Id.*

[680] *See* 42 CFR 460.64(a)(3).

[681] *Id.* at § 460.92(a).

[682] *Id.* at § 460.92(b).

[683] *Id.* at § 460.104(a).

PACE participant. Discriminatory decision-making is inconsistent with these overall standards for how PACE organizations must furnish services.

We believe that expressly prohibiting discrimination based on sexual orientation or gender identity in these regulations could lead to improved health outcomes for PACE participants.[684] Without robust protection from such discrimination, PACE participants may face, or continue to face, barriers to accessing medically necessary health care, and PACE participants who are transgender individuals may face additional barriers to, or be denied, clinically appropriate gender-affirming care.

Sections 1894(f)(4) and 1934(f)(4) of the SSA provide authority for the establishment of beneficiary safeguards to ensure the health and safety of all PACE participants, including ensuring they have access to all required PACE items and services. We are proposing changes to 42 CFR 460.98(b)(3) and 460.112(a) to ensure the health and safety of PACE participants by establishing express protections against discriminatory actions based on sexual orientation and gender identity.

Finally, the Department proposes that if any of the provisions at 42 CFR 460.98(b)(3) and 460.112(a) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from its respective sections and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in these CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including RFRA and all other applicable legal requirements.

C. Insurance Exchanges and Group and Individual Health Insurance Markets

LGBTQI+ people face barriers to obtaining appropriate health care, including access to insurance and coverage for needed services. For these reasons—as discussed in greater detail throughout this preamble related to access to nondiscriminatory health coverage—and given the Department's goal to ensure consistency across its nondiscrimination policies and programs and entities subject to Section 1557 as discussed previously, the Department here proposes to amend 45 CFR 147.104, 155.120, 155.220, 156.200, and 156.1230, so that they explicitly identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex.

The Department proposed similar amendments to these same regulations in the 2023 Payment Notice proposed rule. However, because this proposed rule addressing Section 1557 also would address issues related to prohibited discrimination based on sex, the Department determined that it would be most prudent to address the nondiscrimination proposals related to sexual orientation and gender identity in this proposed rule to ensure consistency across the policies and requirements applicable to entities subject to Section 1557. When issuing a final rule on the provisions proposed in this rule, we intend to also respond to the comments already submitted on the similar proposal included in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

As described above, Section 1557 prohibits discrimination in health programs or activities, any part of which receives Federal financial assistance. Similarly, as the Department noted in the 2020 Rule, CMS also possesses statutory authority to prohibit discrimination in the Exchanges. CMS relies on these authorities for the proposed revisions discussed in section V.C.1 of the preamble.[685] In the respective preambles to §§ 155.120(c), 155.220(j), 156.200(e), and 156.1230(b), CMS identifies and discusses the specific statutory authorities (in addition to Section 1557) that CMS relies upon for the proposals to prohibit discrimination based on sexual orientation and gender identity. Relying on authority separate from Section 1557, CMS also re-proposes the revision and clarification discussed in section V.C.2 of the preamble, related to §§ 147.104 and 156.125. Section 147.104 applies to issuers offering non-grandfathered health insurance coverage in the group and individual markets, and § 156.125 applies to issuers offering non-grandfathered health insurance coverage in the small group and individual markets. Both of these provisions therefore apply to issuers that may not be entities covered by Section 1557. For this reason, CMS does not rely on Section 1557 authority with respect to these provisions.

Finally, the Department proposes that if any of the provisions at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.200(e), or 156.1230(b) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from its respective sections and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in these CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, RFRA and all other applicable legal requirements.

1. Health Insurance Exchanges

a. Non-interference With Federal Law and Nondiscrimination Standards (§ 155.120)

Section 155.120(c) currently provides that in order to avoid interference and comply with applicable nondiscrimination statutes, the states and the Exchanges must not discriminate based on race, color, national origin, disability, age, or sex. Previously, in the final rule ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' (Exchange Standards final rule), pursuant to the authority provided in section 1321(a)(1)(A) of the ACA to regulate the establishment and operation of an Exchange, the Department finalized § 155.120(c) to also prohibit discrimination based on sexual orientation and gender identity.[686] The 2020 Rule removed the terms ''sexual orientation'' and ''gender identity'' from the regulation text. For the reasons stated earlier in section V.C. of the preamble, for consistency with the proposals elsewhere in this proposed rule, to ensure that sexual orientation and gender identity are added, and to promote consistency across HHS programs, we propose to amend 45 CFR 155.120(c) by revising ''sex'' to ''sex (including sexual orientation and gender identity)''.

In addition to the Section 1557 authority discussed above, section 1312(a)(1)(A) of the ACA also authorizes CMS to prohibit discrimination in Exchanges pursuant to the authority to establish requirements with respect to the operation of Exchanges.[687] Pursuant

[684] Brian W. Ward et al., U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, National Health Statistics Report: Sexual Orientation & Health Among U.S. Adults: National Health Interview Survey, 2013 (2014), *https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.*

[685] 85 FR 37160, 37219, 37218–21 (June 19, 2020).

[686] 77 FR 18310 (Mar. 27, 2012).

[687] 85 FR 37218–21.

to this authority, HHS finalized in the Exchange Standards final rule that a State must comply with any applicable nondiscrimination statutes, specifically finalizing that a State must not operate an Exchange in such a way as to discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. CMS proposes to exercise that same authority here to amend § 155.120(c) to again prohibit states and Exchanges carrying out Exchange requirements from discriminating based on sexual orientation and gender identity. Section 1321(a)(1)(A) of the ACA is the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 155.120(c) that currently prohibit discrimination on the basis of race, color, national origin, disability, age, or sex.

We seek comment on this proposal. However, we note that the Department proposed similar amendments to this section in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

b. Federally-Facilitated Exchange Standards of Conduct (§ 155.220)

Section 155.220(j)(2)(i) currently states that an agent, broker or web-broker that assists with or facilitates enrollment through a Federally-facilitated Exchange or assists individuals in applying for advance payment of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchange, QHPs offered through the Federally-facilitated Exchange, 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 to believe they are visiting HealthCare.gov), coercive, or discriminates based on race, color, national origin, disability, age, or sex. This provision also applies to agents, brokers, and web-brokers in State-based Exchanges on the Federal platform under § 155.220(l). Previously, in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (2017 Payment Notice final rule),[688] we finalized § 155.220(j)(2)(i) to also prohibit discrimination based on sexual orientation and gender identity. The 2020 Rule removed the terms ''sexual orientation'' and ''gender identity'' from the regulation text. For the reasons stated earlier in section V.C. of the preamble, for consistency with the proposals elsewhere in this proposed rule, to ensure that sexual orientation and gender identity are added, and to promote consistency across HHS programs, the Department proposes to amend 45 CFR 155.220(j)(2)(i) by revising ''sex'' to ''sex (including sexual orientation and gender identity)''.

In addition to Section 1557 authority discussed above, section 1312(e) of the ACA grants CMS independent statutory authority to establish procedures for States to permit agents and brokers to enroll consumers in QHPs through the Federally-facilitated Exchanges, as described in Sections 1312(e) of the ACA, and the authority to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate under Sections 1321(a)(1)(A), (B), and (D) of the ACA. Pursuant to this authority, in the 2017 Payment Notice final rule, HHS finalized at § 155.220 standards of conduct for agents and brokers that assist consumers to enroll in coverage through the Federally-facilitated Exchanges to protect consumers and ensure the proper administration of the Federally-facilitated Exchanges, including nondiscrimination standards at § 155.220(j)(2)(i) that prohibited agents, brokers and web-brokers described in paragraph (j)(1) from discriminating based on sexual orientation and gender identity. CMS further explained that such standards of conduct were necessary to protect against agent and broker conduct that is harmful towards consumers, or that prevents the efficient operation of the Federally-facilitated Exchanges. CMS proposes to exercise that same authority here to amend § 155.220(j)(2)(i) to again prohibit an individual or entity described in paragraph (j)(1) from discriminating based on sexual orientation and gender identity. Sections 1312(e) and 1321(a)(1)(A), (B), and (D) of the ACA are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 155.220(j)(2)(i).

We seek comment on this proposal. However, we note that the Department proposed similar amendments to this section in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

c. QHP Issuer Participation Standards (§ 156.200)

Section 156.200(e) states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. Previously, in the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' (2012 Exchange Standards) final rule, we finalized § 156.200(e) to also prohibit discrimination based on sexual orientation and gender identity.[689] In the ''Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule'' (EHB final rule), we finalized at § 156.125 that the nondiscrimination requirements in § 156.200 also apply to all issuers required to provide coverage of EHB, thereby prohibiting discrimination based on factors such as sexual orientation and gender identity.[690] (See further discussion of § 156.125 in section V.C.2 of this preamble.) The 2020 Rule removed the terms ''sexual orientation'' and ''gender identity'' from the regulation text. For the reasons stated earlier in section V.C. of the preamble, for consistency with the proposals elsewhere in this proposed rule, to ensure that sexual orientation and gender identity are added, and to promote consistency across HHS programs, we propose to amend 45 CFR 156.200(e) by revising ''sex'' to ''sex (including sexual orientation and gender identity)''.

In addition to the Section 1557 authority discussed above, section 1311(c)(1)(A) of the ACA gives CMS the statutory authority to prohibit discrimination by QHP issuers. Accordingly, CMS requires QHP issuers to comply with applicable state laws and regulations regarding marketing by health insurance issuers and not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. CMS is authorized to interpret and implement this requirement, and to set additional requirements for QHPs under its authority to establish requirements with respect to the offering of QHPs through the Exchanges in section 1321(a)(1)(B) of the ACA.[691] Pursuant to this authority to set QHP standards in

[688] 81 FR 12204 (May 9, 2016).

[689] 77 FR 18310.

[690] 78 FR 12834 (Feb. 25, 2013).

[691] 85 FR 37218–37221.

section 1321(a)(1)(B) of the ACA, HHS finalized in the 2012 Exchange Standards final rule requirements at § 156.200(e) intended to protect enrollees and potential enrollees from discriminatory practices, including on the basis of sexual orientation and gender identity. CMS proposes to exercise that same authority here to amend § 156.200(e) to again prohibit QHPs from discriminating based on sexual orientation and gender identity. Section 1321(a)(1)(B) of the ACA is the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 156.200(e).

We seek comment on this proposal. However, we note that the Department proposed similar amendments to this section in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

d. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

Section 156.1230(b)(2) states that the QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchange, QHPs offered through the Federally-facilitated Exchange, and insurance affordability programs, and refrain from marketing or conduct that is misleading a consumer into believing they are visiting *HealthCare.gov,* coercive, or discriminates based on race, color, national origin, disability, age, or sex. Previously, in the 2017 Payment Notice final rule (81 FR 12203 (May 9, 2016)), HHS finalized at § 155.220(j)(2)(i) standards that prohibited agents, brokers and web-brokers from discriminating on the basis of sexual orientation and gender identity, among other factors. In the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 (2018 Payment Notice final rule), we added this nondiscrimination standard from § 155.220(j) to § 156.1230(b), so that the nondiscrimination protections on the basis of sexual orientation and gender identity also applied to issuers using direct enrollment on a Federally-facilitated Exchange.[692] The 2020 Rule removed the terms ''sexual orientation'' and ''gender identity'' from the regulation text. For the reasons stated earlier in section V.C. of the preamble, for consistency with the proposals elsewhere in this proposed rule, to ensure that sexual orientation and gender identity are added, and to promote consistency across HHS programs, we propose to amend 45 CFR 156.1230(b)(2) by revising ''sex'' to ''sex (including sexual orientation and gender identity)''.

In addition to Section 1557 authority discussed above, section 1321(a)(1)(A), (B), and (D) of the ACA gives CMS statutory authority to prohibit discrimination in enrollment through the Exchanges by issuers of QHPs—namely the authority to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate. Pursuant to this authority, in the 2018 Payment Notice final rule, HHS finalized at § 156.1230(b)(2) standards applicable to issuers using direct enrollment on a Federally-facilitated Exchange to require that issuers refrain from marketing or conduct that is misleading, coercive, or discriminatory, including on the basis of sexual orientation or gender identity. HHS explained it was adding this nondiscrimination standard from § 155.220(j) to § 156.1230(b) so that the nondiscrimination protections on the basis of sexual orientation and gender identity also applied to issuers using direct enrollment on a Federally-facilitated Exchange. HHS proposes to exercise that same authority here to amend § 156.1230(b) to again prohibit issuers using direct enrollment on a Federally-facilitated Exchange from discriminating based on sexual orientation and gender identity. Sections 1321(a)(1)(A), (B), and (D) of the ACA are the same authority CMS relies upon for implementation of existing nondiscrimination protections at § 156.200(e).

We seek comment on this proposal. However, we note that the Department proposed similar amendments to this section in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

2. Prohibition of Discrimination—Group and Individual Health Insurance Markets

a. Guaranteed Availability of Coverage (§ 147.104)

Section 147.104(e) states that a health insurance issuer and its officials, employees, agents, and representatives must not 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. Pursuant to section 1311(c)(1)(A) of the ACA, the HHS Secretary was required to establish by regulation criteria for certification that require QHP issuers to meet marketing requirements and not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs. As discussed in section V.C.2.c. of this preamble, under the authority of section 1321(a) of the ACA, which provides the HHS Secretary broad rulemaking authority with respect to the establishment and operation of Exchanges and the offering of QHPs through such Exchanges, in the 2012 Exchange Standards final rule, CMS codified a regulation implementing prohibitions on discrimination by QHP issuers at §§ 156.200(e) and 156.225(b).[693] Under the authority in section 2702 of the PHS Act as well as the general rulemaking authority in section 2792 of the PHS Act, which provides the HHS Secretary broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, the ''Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review'' final rule adopted a similar standard in § 147.104(e), applying this requirement market-wide to issuers offering non-grandfathered plans in the group and individual health insurance markets, regardless of whether the coverage is offered through or outside of an Exchange.[694]

For the proposal to amend § 147.104, CMS relies on its authorities under sections 2702 and 2792 of the PHS Act, which provide the HHS Secretary broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act. These are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 147.104(e). Utilizing these same authorities to again prohibit discrimination based on sexual orientation and gender identity would be consistent with the authority CMS relies upon for those existing

[692] 81 FR 94058 (Dec. 22, 2016).

[693] 77 FR 18310.

[694] 78 FR 13406 (Feb. 27, 2013).

protections at § 147.104(e) that currently prohibit discrimination on the basis of 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.

CMS does not propose to rely on Section 1557 authority for this amendment for two primary reasons. First, § 147.104 applies to non-grandfathered health insurance coverage in the individual or group market, and not all of such issuers will receive Federal financial assistance such that they would be subject to Section 1557. Second, under PHS Act section 2723, states have primary enforcement authority over issuers with respect to regulations implementing title XXVII of the PHS Act, including § 147.104. If CMS determines that a state is not substantially enforcing a provision in title XXVII, then CMS may enforce the provision's requirements. Because states would not have authority to enforce Section 1557, CMS is of the view that partial reliance on Section 1557 authority could unnecessarily complicate enforcement efforts.

For the reasons stated earlier in section V.C. of the preamble, for consistency with the proposals elsewhere in this proposed rule, to ensure that sexual orientation and gender identity are added, and to promote consistency across HHS programs, we propose to amend 45 CFR 147.104(e) by revising ''sex'' to ''sex (including sexual orientation and gender identity)''.

We seek comment on this proposal. However, we note that the Department proposed similar amendments to this section in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

b. Prohibition on Discrimination (§ 156.125)

Elsewhere in this rule, we propose to amend § 156.200(e) to prohibit discrimination based on sexual orientation and gender identity. If these proposed nondiscrimination protections are finalized, § 156.125(b) would accordingly require issuers providing EHB to comply with such nondiscrimination requirements. Specifically, § 156.125(b) states that an issuer providing EHB must comply with the requirements of § 156.200(e), which currently states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. HHS previously codified nondiscrimination protections based on sexual orientation and gender identity at § 156.200(e), simultaneously requiring that issuers providing EHB comply with such requirements by virtue of the cross-reference in § 156.125(b) to § 156.200(e). The 2020 Rule amendments removed from § 156.200(e) any reference to sexual orientation and gender identity. As discussed in section V.C.1.c of the preamble, we propose to amend 45 CFR 156.200(e) by revising ''sex'' to ''sex (including sexual orientation and gender identity)''.

If the proposals at § 156.200(e) are finalized, issuers providing EHB would again be required under § 156.125(b) to comply with nondiscrimination protections in § 156.200(e) that prohibit discrimination on the basis of sexual orientation and gender identity.

Section 1302(b) of the ACA also gives CMS the statutory authority to prohibit discrimination in the small group and individual markets pursuant to the authority to define EHB at section 1302(b) of the ACA. The statute specifies that in defining EHB the Secretary must take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups. The EHB requirements apply to non-grandfathered health insurance coverage in the individual and small group markets under section 2707(a) of the PHS Act. CMS has the authority to interpret and implement these provisions under its general rulemaking authorities in sections 1321(a)(1)(B) and (D) of the ACA and section 2792 of the PHS Act. Pursuant to those authorities, HHS finalized in the EHB final rule that § 156.125 prohibits benefit discrimination on the grounds articulated by Congress in section 1302(b)(4) of the ACA, as well as those in § 156.200(e), which at the time included race, color, national origin, disability, age, sex, gender identity, and sexual orientation. It is under that same exercise of authority here that § 156.125 would again prohibit discrimination on the basis of sexual orientation and gender identity if the proposed changes to include such factors in the nondiscrimination protections at § 156.200(e) are finalized. Sections 1302(b) and 1321(a)(1)(B) and (D) of the ACA and sections 2707(a) and 2792 of the PHS Act are the same authorities CMS relies upon for implementation of existing nondiscrimination protections at § 156.125. Relying on these same authorities to again prohibit discrimination based on sexual orientation and gender identity at § 156.125 by cross-reference to the nondiscrimination protections at § 156.200(e) would be consistent with the authority CMS relies upon for the existing protections at § 156.125 that prohibit discrimination on the basis of race, color, national origin, disability, age, or sex by cross-reference to § 156.200(e).

CMS does not rely on Section 1557 authority for this amendment for the same two primary reasons described in section V.C.2.a of this preamble. First, § 156.125 applies to issuers offering non-grandfathered health insurance coverage in the individual or small group market, and not all of such issuers will receive Federal financial assistance such that they would be subject to Section 1557. Second, under PHS Act section 2723, states have primary enforcement authority over issuers with respect to regulations implementing title XXVII of the PHS Act, including § 156.125. If CMS determines that a state is not substantially enforcing a provision in title XXVII, then CMS may enforce the provision's requirements. Because states would not have authority to enforce Section 1557, CMS is of the view that partial reliance on Section 1557 authority could unnecessarily complicate enforcement efforts.

We seek comment on this proposal. However, we note that the Department proposed similar amendments to this section in the 2023 Payment Notice proposed rule. Accordingly, there is no need for entities that commented on these proposals in the 2023 Payment Notice proposed rule to submit duplicative comments.

VI. Executive Order 12866 and Related Executive Orders on Regulatory Review

A. Regulatory Impact Analysis

We have examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.'s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is an economically significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs of the proposed rule

are small relative to the revenue of covered entities, including covered small entities, and because even the smallest affected entities would be unlikely to face a significant impact, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) generally requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule is not subject to the Unfunded Mandates Reform Act because it falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability.[695]

The Background and Reasons for the Proposed Rulemaking sections at the beginning of this preamble contain a summary of this proposed rule and describe the reasons it is needed.

1. Summary of Costs and Benefits

This analysis quantifies several categories of costs to covered entities and to the Department under the proposed rule. Specifically, we quantify costs associated with covered entities training employees, revising policies and procedures, and costs associated with notices, including the notice of nondiscrimination and notice of availability of language assistance services and auxiliary aids and services. We quantify costs associated with provisions of the proposed rule related to documenting training activities performed under the proposed rule. We also quantify incremental costs associated with expanded coverage for gender-transition-related medical care. We conclude that the proposed rule would result in annualized costs over a 5-year time horizon of $560 million or $551 million, corresponding to a 7% or a 3% discount rate. This analysis also addresses uncertainty in costs associated with notices and expanded gender-transition-related medical care, which is discussed in greater detail in the main body of the analysis. We separately report a full range of cost estimates of about $427 million to $1,093 million using a 7% discount rate, and a full range of cost estimates of about $417 million to $1,084 million using a 3% discount rate.

In addition to these quantified cost estimates, the main analysis includes a discussion of costs that we do not quantify, and a discussion of the potential benefits under the rule that we similarly do not quantify. In addition to the impacts that we quantify, this proposed rule could also result in increases in premiums, which would result in increases in Exchange user fees and Federal expenditures for advance payments of the premium tax credit. We request comments on our estimates of the cost and benefits of this proposed rule, including the impacts that are not quantified in this analysis.

TABLE 1—ANNUALIZED COSTS OF THE PROPOSED RULE

[$ millions/year (percent)]

Primary estimate	Low estimate	High estimate	Year dollars	Discount rate	Period covered (percent)
$560	$427	$1,093	2020	7	2024–2028
551	417	1,084	2020	3	2024–2028

a. Baseline Conditions

Section 1557 prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. It applies to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA.[696] On May 18, 2016, the Department published a final rule to implement Section 1557 under the statute and 5 U.S.C. 301. On June 19, 2020, the Department published a final rule that revised the Department's approach to implementing Section 1557. As described in the Background section of this preamble in greater detail, neither final rule was fully implemented as published, and certain provisions of the 2020 Rule remain the subject of ongoing litigation. The Background section of the preamble also discusses the Department's May 10, 2021 Bostock Notification, in accordance with the Supreme Court's decision in *Bostock* and based on the plain language of Title IX, that the Department would interpret Section 1557's prohibition on sex discrimination to include (1) discrimination on the basis of sexual orientation and (2) discrimination on the basis of gender identity.[697]

The baseline scenario of no further regulatory action is substantially informed by the RIAs published with the 2016 and 2020 Rules. The 2016 RIA identified five sources of monetized costs: training and familiarization, enforcement, notice publication, sex discrimination policy and procedure changes, and language access plans. The bulk of the monetary impacts identified in the 2016 RIA occur in the first two years under the final rule, with costs continuing in future years only for enforcement and language access plans.

The 2020 RIA adopted many of the assumptions contained in the 2016 RIA. For example, it assumed that many of the initial activities anticipated under the 2016 rule were performed, and that the first two years of costs attributable to the 2016 Final Rule were incurred.[698] The 2020 RIA identifies cost savings only ''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.'' The 2020 RIA also identifies costs in the first year ''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.''

In establishing a baseline scenario, this analysis similarly maintains a number of assumptions and estimates contained in prior analyses. For

[695] 2 U.S.C. 1503(2).

[696] 42 U.S.C. 18116.

[697] 86 FR 27984 (May 25, 2021).

[698] *E.g.,* 85 FR 37160, 37235 (June 19, 2020) (''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.'').

example, the baseline scenario includes some ongoing costs that are attributable to the 2016 Rule, such as the costs of enforcement. The 2016 RIA estimated that the costs of enforcement would be $98.2 million (reported in 2020 dollars), which we adopt as the costs under both the baseline and proposed rule scenarios. Similarly, we adopt the assumption in the 2020 RIA that covered entities continue to provide ongoing training attributable to the 2016 Rule, which was not impacted by the 2020 Rule. We include these ongoing training activities, including annual refresher training for returning employees and training for new employees, in the baseline scenario of no regulatory action. In the next section, we discuss the incremental costs of the proposed rule, which exclude ongoing costs attributable to prior rulemaking.

b. Costs of the Proposed Rule

This analysis anticipates that the proposed rule would result in one-time costs to covered entities to train employees and revise policies and procedures. The proposed rule would result in costs associated with a revised approach to notices, including the notice of nondiscrimination and notice of availability of language assistance services and auxiliary aids and services. The proposed rule would also result in costs associated with provisions related to documenting training activities performed under the proposed rule. The proposed rule might result in additional costs associated with expanded coverage for gender-transition-related medical care. We discuss the potential costs associated with this expanded coverage and the potential that some or all of these costs would be offset by reductions in spending on other types of care. The analysis also discusses other potential costs of the proposed rule that we do not quantify.

Training

The Department anticipates that some covered entities would incur costs to train or retrain employees under the proposed rule. To calculate the costs related to training, we follow an approach common to both the 2016 and 2020 RIAs. Both analyses adopted an estimate of 275,002 covered entities that would train their employees on the requirements and used this figure as the basis for calculating the total costs. The 2020 RIA adjusted this figure downwards by 50%, anticipating that some covered entities would not modify their procedures in response to the 2020 Final Rule, and would therefore not need to offer new training. Both RIAs anticipated that employers would most likely train employees who interact with the public and recognized that the percentage of employees that interact with patients and the public vary by covered entity. To account for this, the analyses adopted a central estimate of 50% of staff at covered entities that received one-time training on the requirements of the regulation.

Both RIAs reported the number of employees at covered entities by occupation category. To monetize the total costs of training, the RIAs adopted a value of time based on the average fully loaded wage rate for each occupation, combined with an assumption about the duration of the training. The 2016 RIA assumed that 50% of total employees at covered entities would receive training, while the 2020 RIA assumed that 25% of employees would receive training. Both RIAs assumed the typical training would last one (1) hour. For the purpose of this analysis, we assume that 75% of total employees at covered entities would receive training, and that this training would last one (1) hour. This estimate is consistent with an assumption that all covered entities would revise their policies and procedures under the proposed rule, and that most employees at covered entities would receive training.

As a necessary first step in calculating the incremental total costs of training attributable to the proposed rule, we have collected the most recent available data on the number of employees that would likely undergo training under the proposed rule, and data on the average wage rate by occupation for these employees.

The first category of health care staff that may receive training comprises health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The U.S. Bureau of Labor Statistics (BLS) Occupational code for this grouping is 29–1000, and the 2020 reported count for this occupational group is approximately 5.6 million, with average loaded wages of $101.16 per hour.

The second category of health care staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29–2000) and accounts for 2.9 million workers with average loaded wages of $47.10 per hour. Technicians work in almost every area of health care: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. The Department refers to this workforce as non-degreed, compared to medical technicians who generally have degrees or certificates. There are approximately 5.9 million individuals employed in these occupations in the health care and social assistance sector, with average loaded wages of $30.72 per hour.

The fourth category of health care staff that the Department assumes will receive training is health care managers (approximately 0.4 million individuals based on BLS data for Occupation code 11–9111), with average loaded wages of $114.24 per hour.

The fifth category of health care staff that the Department assumes will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.7 million individuals were employed in these occupations in health facilities in 2020, with average loaded wages of $38.50 per hour. The Department assumes that outreach workers are included in the five categories listed above.

These figures sum to 17.4 million employees at covered entities, of which we assume 13.1 million would receive training attributable to the proposed rule. Across the five occupation categories, we compute a weighted hourly wage rate of $29.59, or a weighted fully loaded hourly wage rate of $59.18. Assuming that the average training takes one (1) hour and adopting a value of time based on fully loaded wage rates, we estimate the total cost of training of about $775 million, which would be incurred in the first year. As a sensitivity analysis, we considered the scenario of covered entities providing training to all employees, not just employees who interact with the public. Under this scenario, the total cost of training would increase, to about $1.0 billion. These costs are likely overstated since this training may supplement or replace expected annual or other ongoing training activities at covered

entities. To the extent that covered entities reduce time spent on other training activities, these costs would offset some of the total costs attributable to the proposed rule.

In addition to the first-year training costs, we anticipate that the proposed rule would result in additional costs associated with ongoing training, including annual refresher training for returning employees or and training for new employees. As discussed in the Baseline Conditions section, we assume that many covered entities are routinely carrying out these activities, absent further regulatory action. However, we anticipate that the proposed rule would result in a larger share of employees at covered entities receiving such training. To quantify the change in training activities between the baseline scenario and the proposed rule scenario, we take the difference between the share of employees receiving training under the baseline scenario and the proposed rule scenario. We carry through an assumption from the 2016 RIA, which assumed that 50% of total employees at covered entities receive training and compare this to an assumption in this proposed RIA that 75% of total employees at covered entities would receive training. This yields an estimate of 25% of total employees at covered entities that would receive training in subsequent years under the proposed rule. We adopt the same weighted hourly wage estimate, number of employees, and estimate the total cost of ongoing annual training costs of $258 million. These costs would occur in years two through five in the time horizon of this analysis.

Revising Policies and Procedures

As discussed above, the Department anticipates that all covered entities, or approximately 275,002 entities, would revise their policies and procedures under the proposed rule, with half of these entities requiring fewer revisions. For covered entities with more extensive revisions, we adopt the estimates contained in the 2020 RIA, with four (4) total hours spent on revisions per entity. Of these, three would be spent by a mid-level manager equivalent to a first-line supervisor (Occupation code 43–1011), at a cost of $56.96 per hour after adjusting for non-wage benefits and the indirect costs, 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 $104.80 per hour after adjusting for non-wage benefits and indirect costs. For covered entities with less extensive revisions, we assume two total hours spent on revisions per entity. Of these, one would be spent by a mid-level manager, and one would be spent by executive staff.

We monetize the time spent on revising policies and procedures by estimating a total cost per entity of $275.68 or $161.76, depending on the extent of the revisions. For the 137,501 covered entities with more extensive revisions, we estimate a cost of about $37.9 million. For the 137,501 covered entities with less extensive revisions, we estimate a cost of about $22.2 million. We estimate the total cost associated with revisions to policies and procedures under the proposed rule of $60.1 million.

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.

Notices

The proposed rule would require a covered entity to provide a notice of nondiscrimination to participants, beneficiaries, enrollees, and applicants of its health program or activity, and members of the public. It also would require the 275,002 covered entities to provide a notice of availability of language assistance services and auxiliary aids and services. These provisions resemble elements of the 2016 Rule that were repealed in the 2020 Rule; however, the approach under the proposed rule provides a narrower set of situations where covered entities would be required to provide these notices. Both types of notices are required (1) on an annual basis; (2) upon request; (3) at a conspicuous location on the covered entity's health program or activity website; and (4) in clear and prominent physical locations where the health program or activity interacts with the public.

The notice of availability of language assistance services and auxiliary aids and services is required in the following electronic and written communications related to the covered entity's health programs and activities: (1) notice of nondiscrimination required by proposed § 92.10; (2) notice of privacy practices required by 45 CFR 164.520; (3) application and intake forms; (4) notices of denial or termination of benefits or services, including Explanations of Benefits (EOBs) and notices of appeal and grievance rights; (5) communications related to a person's rights, eligibility benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant; (6) communications related to a public health emergency; (7) consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together); (8) discharge papers; (9) complaint forms; and (10) patient and member handbooks.

For the purposes of the analysis, we base our estimates of the number of communications containing these notices on a subset of the communications identified in the 2020 RIA. We include communications that are EOBs. The Department received feedback regarding the financial burden imposed by applying the notice and tagline requirements to EOBs. EOBs are typically an individual's first, and often only, notice of a denial or termination of benefits or services, and as such the notice and tagline requirements are essential in this context to ensure timely and equitable access to appeals processes. Covered entities may provide individuals with the option to opt out of receiving these notices on an annual basis, which will reduce the cost and burden associated with these requirements. In addition, as enrollees, participants, and beneficiaries increasingly elect to receive EOBs electronically, we expect the cost of these requirements to decrease over time. We adopt the other estimates as a reasonable proxy for the number of communications that would be anticipated under the proposed rule. These estimates are intended to encompass all categories of notices required under the proposed rule. Table 2 below reports the number of communications containing notices anticipated under the proposed rule and presents the costs of these communications. Our cost estimates reflect a wide range of uncertainty in the cost per communication. For our primary scenario, we adopt a central estimate of the average costs to print and fold paper forms containing prescribing information of $0.05 (calculated as the midpoint estimate of a range from $0.03 to $0.07), reported in 2010 dollars.[699] We explore the

[699] U.S. Dep't of Health & Human Servs., Food & Drug Admin., Electronic Distribution of Prescribing Information for Human Prescriptions Drugs, Including Biological Products (Proposed Rule), 79 FR 75506 (Dec. 18, 2014).

sensitivity of the overall cost estimates under a low-cost ($0.035 per unit) and high-cost ($0.32 per unit) scenario, reported in 2018 dollars, which matches the range contained in the 2020 RIA. We adjust these per-unit cost inputs for inflation to 2020 price levels using the Implicit Price Deflator, resulting in a primary per-unit cost estimate of about $0.06 and a full range of about $0.04 to $0.33.[700] Combining these per-unit cost estimates with the count of each notice results in a primary estimate of $78.4 million, with a range of estimates between $47.8 million and $437.2 million. Following the approach in the 2020 RIA, we adjust this figure downwards by 50% to account for the lower cost of electronic communications. For this adjustment, we adopt a measure of the share of respondents reporting that they used a ''Digital (mobile app or website)'' method to contact or interact with their health care insurer in the last year when viewing an online statement.[701] We anticipate that the share of communications occurring online will increase over time, but have not accounted for a trend for the 5-year time horizon of this analysis. This adjustment results in a primary estimate of the adjusted annual total of $78.4 million, with a range of costs between $23.9 million and $218.6 million. These costs would occur in each year of the time horizon of the analysis.

TABLE 2—COST OF NOTICE PROVISIONS

[2020 dollars]

Cost element	Count (millions)	Cost scenario ($ millions)		
		Low	Primary	High
Eligibility and enrollment communications	17.7	$0.7	$1.1	$6.0
Annual notice of benefits	123.0	4.6	7.5	41.8
Explanations of benefits—hospital admissions	96.0	3.6	5.8	32.6
Explanations of benefits—physician visits	941.0	34.9	57.3	319.5
Medical bills—hospital admissions	11.0	0.4	0.7	3.7
Medical bills—physician visits	99.0	3.7	6.0	33.6
Total, Unadjusted	1287.7	47.8	78.4	437.2
Total, Adjusted for Electronic Delivery	1030.2	23.9	39.2	218.6

Documentation Requirements

The proposed rule would require covered entities to contemporaneously document certain other activities performed under the proposed rule. This includes activities such as employees' completion of the training required by this section in written or electronic form. The proposed rule also requires covered entities to retain certain records. These and other requirements, and the associated cost estimates, are discussed in greater detail in the PRA Section.

The costs associated with retaining records related to grievances filed with a covered entity is the time spent by the staff of covered entities to store the complaints for no less than three (3) years. We calculate the costs of labor as one (1) employee per covered entity with more than 15 employees (41,250)[702] spending 10 hours to store complaints and the associated records required under proposed § 92.8(c)(2) each year. We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $17.38 per hour, which we double to account for overhead and other indirect costs. We estimate the costs of retaining records related to grievances filed at all covered entities would be $14.3 million annually ($17.38 × 2 × 10 × 41,250). This estimation approach will overstate the costs if many covered entities already retain complaint information.

The costs associated with documenting employee training is the time spent by the staff of covered entities to (a) create training attendance forms; and (b) store the training sign-up sheet. We calculate the costs of labor as one (1) employee spending 15 minutes (0.25 hours) to create the sign-up sheet during the first year and one (1) employee spending one (1) hour collecting and storing the attendance forms the first year and subsequent years. We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $17.38 per hour, which we double to account for overhead and other indirect costs. We estimate the costs of documenting employee training would be $11.9 million in the first year ($17.38 × 2 × 1.25 × 275,002) and $9.6 million in subsequent years ($1.738 × 2 × 1 × 275,002).

Expanding Coverage for Gender-Transition-Related Medical Care

In addition to the cost some covered health insurance issuers and plans may incur for revising policies and procedures to comply with the rule, there is a possibility that such issuers and plans may incur a *de minimis* cost related to the cost of coverage for gender-transition-related medical care. Various studies, however, suggest that any such increased costs will likely be negligible, and that any increases may be offset by savings from decreased utilization of other services.

In April 2012, the California Department of Insurance conducted an Economic Impact Assessment on Gender Nondiscrimination in Health Insurance that found that covering transgender individuals under California's private and public health insurance plans would have an ''insignificant and immaterial'' impact on costs.[703] This conclusion was based

[700] *Gross Domestic Product: Implicit Price Deflator (GFPDEF),* Fed. Reserve Bank of St. Louis, *https://fred.stlouisfed.org/series/GDPDEF* (last visited June 15, 2022).

[701] Saurabh Gupta et al., HFS Res. & Cognizant, Health Consumers Want Digital: It's Time for Health Plans to Deliver, p. 4 (2021), *https://www.cognizant.com/us/en/documents/hfs-health-consumers-want-digital-its-time-for-health-plans-to-deliver.pdf.*

[702] This estimate is consistent with the 2016 Rule's Regulatory Impact Analysis: ''Of the 275,002 covered entities, approximately 15% employ more than 15 employees, resulting in approximately only slightly more than 41,250 covered entities being required to have grievance procedures and designate a responsible official.'' 81 FR 31375, 31452 (May 18, 2016).

[703] State of Cal., Dep't of Ins., Economic Impact Assessment Gender Nondiscrimination in Health Insurance, p. 1 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022% and 0.0173%.[704] The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-affirming health care differs according to the needs and pre-existing conditions of each individual.[705] Despite expecting a possible spike in demand for benefits due to former or current unmet demand, the California Insurance Department concluded that any increased utilization that might occur over time is likely to be so low that any resulting costs remain actuarially immaterial.[706] The Assessment notes the experience of one employer that initially established premium surcharges to cover the anticipated cost of transition-related care, reporting that the employer subsequently eliminated the surcharges because they found that the funds collected were nearly 15 times the amount expended on care.[707] While it did not analyze any original data, a 2018 analysis by the state of Wisconsin's Department of Employee Trust Funds cited numerous studies finding that the cost of coverage was minimal, and noted that ''[w]hile it is challenging to predict the costs of care averted for any condition, there is some evidence that the costs associated with providing transgender-inclusive plans is met with reduced costs related to comorbidities.'' [708]

Other studies looking at both public and private sector plans have reached similar conclusions. One study published in the New England Journal of Medicine projected that the cost for providing gender-transition-related health care benefits to members of the military would result in an annual increase of 0.012% of health care costs, ''little more than a rounding error in the military's $47.8 billion annual health care budget.'' [709] A 2013 study of 34 public and private sector employers that provided nondiscriminatory health care coverage found that providing gender-transition-related benefits to treat gender dysphoria had ''zero to very low costs.'' [710] A study comparing costs and potential savings associated with covering gender-transition-related care concluded that projected ''additional expenses hold good value for reducing the risk of negative endpoints—HIV, depression, suicidality, and drug abuse'' and noted that ''provider coverage was cost-effective in 85% of simulations.'' [711] More recently, a 2021 survey of employers conducted by the Human Rights Campaign noted that most employers who covered gender-transition-related care reported only ''marginal increases'' in cost, on the order of ''a fraction of a decimal point of cost calculations.'' [712]

In recent years, some courts hearing challenges to coverage exclusions have also considered issues of cost and concluded that covering gender-transition-related care does not significantly increase costs for plans. In discussing the parties' experts on the issue of the cost, one court noted that, ''[f]rom an actuarial perspective, there appears to be no dispute that the cost of coverage is immaterial.'' [713] Another court reviewing expert testimony called any cost savings from excluding coverage for gender-affirming care ''both practically and actuarially immaterial.'' [714]

Based on the studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment would have a small impact on the overall cost of care and on health insurance premiums in terms of the percentage of overall spending. The utilization rate of newly covered services is likely to be extremely low because the transgender individuals represent a small minority in the general population, because not all transgender individuals will seek medical care in the course of their transition, and because most entities will provide such care regardless of this proposed rule (*i.e.,* they will not otherwise have engaged in prohibited sex discrimination).[715]

As described in this section, the costs associated with additional coverage of services are likely to be small on a percentage basis; however, when these estimates are combined with measures of overall health care spending, they would likely result in incremental costs that could be substantial. As an initial estimate, we pair the Belkin (2015) estimate of 0.012% of incremental health care costs with $3,931.3 billion in total health consumption expenditures in calendar year 2020.[716] Combining these yields our upper-bound estimate of $472 million in annual costs associated with additional coverage. As a lower-bound estimate, we adopt an assumption that these costs will be fully offset by reductions in spending on other medical care. This lower bound of $0 is broadly consistent with a cost-effectiveness analysis that includes the probability of negative incremental costs associated with coverage.[717] For our primary estimate, we start with the midpoint of the lower-bound and upper-bound cost estimate of about $236 million annually. We reduce this figure by half to account for several factors, such as some covered entities already covering transition-related services under the baseline scenario, whether or not this is in response to an existing requirement. This results in a primary estimate of about $118 million per year in incremental annual costs associated with additional coverage under the proposed rule, with a full range of cost estimates including $0 million and $472 million.

[704] *Id.* at p. 3. More recent estimates indicate that a higher share of the population in the United States identifies as transgender (0.6% of the U.S. adult population), Andrew R. Flores et al., The Williams Inst., UCLA Sch. of Law, Race and Ethnicity of Adults Who Identify as Transgender in the United States, p. 2 (2016), *https://williamsinstitute.law.ucla.edu/wp-content/uploads/Race-Ethnicity-Trans-Adults-US-Oct-2016.pdf.*

[705] State of Cal., Dep't of Ins., *supra* note 703, at p. 8.

[706] *Id.* at p. 9.

[707] *Id.* at pp. 6–7.

[708] State of Wis., Dep't of Employee Trust Funds, Correspondence Memorandum Re: Transgender Services Coverage, p. 6–8 (Aug. 14, 2018), *https://etf.wi.gov/boards/groupinsurance/2018/08/22/item6a1/download?inline=.*

[709] Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care,* 373 New Eng. J. Med. 1089 (2015), *https://www.nejm.org/doi/pdf/10.1056/NEJMp1509230?articleTools=true.*

[710] Jody Harman, The Williams Inst., UCLA Sch. of Law, Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers, p. 2 (Sept. 2013), *http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.*

[711] William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis,* 31 J. of Ged. Internal Med. 394 (2015),

[712] Human Rights Campaign, Corporate Equality Index 2021 (2021), *https://reports.hrc.org/corporate-equality-index-2021?_ga=2.206988627.1166715317.1639876655-819100514.1639876655.*

[713] *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

[714] *Flack* v. *Wisconsin Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1021 (W.D. Wis. 2019); *see also Kadel* v. *Folwell,* No. 1:19–cv–00272, 2022 WL 2106270, at *22 (''in comparison to the [Defendant state health plan]'s billion-dollar cash balance and saves each of the Plan's 740,000 members about one dollar each'').

[715] State of Cal., Dep't of Ins., *supra* note 703, at pp. 2, 5.

[716] U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Table 1. National Health Expenditures; Aggregate and Per Capita Amounts, Annual Percent Change and Percent Distribution: Selected Calendar Years 1960–2020, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet* (last modified Dec. 15, 2021, 4:06 p.m.).

[717] Padula, *supra* note 711, at 399 fig. 2.

c. Total Quantified Costs

Table 4 below presents the total costs anticipated under the proposed rule for which estimates have been developed. For the purposes of this analysis, we assume that the regulatory requirements begin to take effect at the start of 2024. In the first year under the proposed rule, these costs include $774.5 million in training and $60.1 million to revise policies and procedures. For all years in the analysis, we estimate recurring costs of $39.2 million related to notices. We estimate a first-year cost of $26.3 million related to documentation, with ongoing costs in future years of $4.8 million. We also report a primary cost estimate of $117.9 million associated with expanded coverage of gender-transition-related care. The total costs in year 1 amount to $1,018.1 million, with ongoing costs of $424.9 million in subsequent years. Table 3 reports these costs by year, with all estimates presented in millions of year-2020 dollars.

TABLE 3—PRIMARY ESTIMATE OF TOTAL ANNUAL COSTS

[$ millions, 2020 dollars]

Cost element	2024	2025	2026	2027	2028
Training	$774.5	$258.2	$258.2	$258.2	$258.2
Policies and Procedures	60.1	0.0	0.0	0.0	0.0
Notices	39.2	39.2	39.2	39.2	39.2
Documentation	26.3	9.6	9.6	9.6	9.6
Expanded Coverage	117.9	117.9	117.9	117.9	117.9
Total Costs	1,018.1	424.9	424.9	424.9	424.9

We also identify a cost related to covered entities submitting a request for an exemption based on Federal conscience or religious freedom laws. We model this potential cost associated with exemption requests as the time spent by covered entities to (a) assess the need for an exemption; (b) write the exemption request; and (c) submit the exemption request to OCR. As an initial calculation, we assume that this would involve two (2) employees spending two (2) hours each assessing the need for an exemption and one employee spending three (3) hours writing and submitting the exemption request to OCR. We further assume that legal personnel, including lawyers and legal assistants, would perform these functions. The mean hourly wage for these occupations is $63.02 per hour for each employee, which we double to account for overhead and other costs. We multiply these factors together and estimate the cost per exemption request of $882.28 ($63.02 × 2 × 7).

OCR receives an average of 428 Section 1557 complaints per year, covering all areas addressed under the statute and regulations. We estimate that about a quarter of these are sex discrimination complaints and anticipate that only a fraction of these correspond to religiously affiliated covered entities, and that not all of these complaints would relate to provision or coverage to which religiously affiliated covered entities would have a religious or conscience objection. As an initial calculation, we estimate that OCR would receive fewer than 27 exemption requests (428 × 0.25 × 0.5 × 0.5), and that these would result in costs to covered entities of $23,601 (multiplying the previous product by $882.28). We include these costs in our assessment of the likely impacts of the proposed rule, but do not itemize these costs in Table 3 as they represent a rounding error compared to other costs we identify. We request public comment on the assumptions in this calculation.

The proposed rule would also explicitly extend the requirements of Section 1557 and other civil rights statutes to entities that are enrolled in Medicare Part B. We are currently unable to quantify the number of covered entities that are enrolled in Part B but that receive no other forms of Federal financial assistance. The 2016 Rule discussed several of the challenges associated with estimating the number of these entities. For example, the 2016 Rule notes that, ''although we have data, by program, for the number of physicians receiving payment from each program, there is no single, unduplicated count of physicians across multiple programs.'' We tentatively adopt the finding of the 2016 Rule that almost all practicing physicians were likely covered by the rule because they accept Federal financial assistance from sources other than Medicare Part B.[718] We request comment and data on the number of entities who are enrolled in Medicare Part B but do not otherwise receive any form of Federal financial assistance.

2. Discussion of Benefits

Quantifying benefits for this proposed rule presents significant challenges. One notable challenge relates to attribution: several sources of benefits discussed in the preambles of the 2016 and 2020 Rules overlap with and may be attributable to prior existing civil rights regulation, to the ACA rather than the 2016 and 2020 rulemakings that implement Section 1557, or to nondiscrimination policies based on state law or institutional policies prohibiting discrimination generally.

A second challenge relates to identifying a quantitative relationship between nondiscrimination policies and important outcomes such as improvements in public health outcomes. For example, we anticipate that this regulation would reduce the incidence of providers refusing to treat patients based on the patient's gender identity. This would result in fewer instances of delayed or denied care, which in turn would lead to reductions in mortality and morbidity risks. However, we are not able to estimate the changes in the magnitude of these discriminatory events that would be attributable to the proposed rule, and thus are unable to quantify or monetize these health improvements. Similarly, we anticipate that the proposed rule will result in other sources of benefits that we are unable to quantify. These include a reduction in suicidal ideation and attempts, improvements to mental health, reductions in substance use, and generally align with a discussion of the economic impacts of a California regulation relating to gender nondiscrimination in health insurance.[719] In addition, the prohibition on discrimination through the use of clinical algorithms is also likely to have a direct benefit on the health of individuals who are suffering from delayed or denied medical care

[718] 81 FR 31375, 31445–46 (May 18, 2016).

[719] State of Cal., Dep't of Ins., *supra* note 703, at pp. 9–11.

due to discriminatory clinical algorithms, though we are unable to quantify this benefit.

These challenges were not resolved in the RIAs associated with the 2016 or 2020 Rules, which only qualitatively reported benefits. We request comments, including data and quantitative estimates of health and quality-of-life improvements attributable to nondiscrimination regulations, that could inform a quantitative analysis, should the Department finalize this proposed rule.

In addition to these health improvements, we anticipate benefits to covered entities from additional regulatory clarity on how OCR will enforce the ACA's nondiscrimination protections, particularly in light of ongoing litigation related to the 2020 Rule, the *Bostock* decision, and the Department's Bostock Notification. The training provisions represent one mechanism by which the proposed rule would reduce discriminatory events. This would, in turn, reduce the number of enforcement actions, representing a potential cost-saving benefit for covered entities. We also anticipate benefits to covered entities from the establishment of a grievance process, which would reduce the number of complaints filed with OCR, though this may be offset somewhat from covered entities with fewer than 15 employees referring complaints to OCR in lieu of adopting their own grievance procedure.

We also anticipate benefits to individuals from reduced obstacles to accessing health care, including fewer language barriers and a reduction in discriminatory behavior related to sexual orientation and gender identity. These benefits relate to individuals' ability to access care and the quality of care they receive. For example, the provisions related to language access for LEP individuals and accessibility for individuals with disabilities could reduce instances of negative outcomes, including death, due to a lack of understanding between patient and doctor or between patient and pharmacist, as well as lack of access to services. We also anticipate that the process by which individuals and recipients may seek an exemption based on Federal conscience and religious freedom laws will result in benefits from reduced litigation, which we do not capture in the cost analysis.

3. Analysis of Regulatory Alternatives to the Proposed Rule

The Department considered various alternatives in the course of developing this regulation. The following are a representative sample of some of those various alternatives considered.

The Department analyzed several regulatory alternatives to the proposed rule related to the notice requirements. The first alternative considered retaining the 2020 Rule repeal of the notices and taglines provisions. The Department considered concerns raised in response to the 2016 Rule notice and tagline requirements, as well as concerns raised in response to the removal of those requirements in the 2020 Rule. Though the Department acknowledges the burden placed on covered entities through the 2016 Rule notice requirements, the Department believes the 2020 Rule did not adequately consider the confusion and uncertainty placed on individuals or the unnecessary ambiguity that covered entities face by the 2020 Rule's repeal of the notices and taglines provisions in their entirety. As described earlier, we estimate that these provisions under the proposed rule would cost covered entities, as an aggregate, $39.2 million for each year. While excluding the provisions relating to the notices would reduce the cost of the proposed rule by $39.2 million, the Department rejected this option because it believes that the proposed provisions strike an appropriate balance between providing greater access for beneficiaries and consumers, while maximizing efficiency and economics of scale for covered entities.

The second alternative considered by the Department would require covered entities to provide notices only at their first encounter with a beneficiary. For this alternative, we adopt the quantity and cost estimates associated with eligibility and enrollment communication included in Table 3 above. Under our primary cost scenario, this policy alternative would result in annual costs of notices of $0.5 million, which is about $38.6 million lower than the proposed rule. The Department rejected this option however, because this policy alternative, while posing a significantly reduced burden on covered entities, would be too narrow and substantially reduce the information available to beneficiaries, likely resulting in beneficiaries not being aware of their civil rights, including whether they have experienced a prohibited discriminatory practice by a covered entity.

The third alternative considered by the Department would require a more expansive notice provision, extending the requirements to include pharmacy-related notices. For this alternative, we adopt the 2020 RIA estimate of 2.9 billion annual pharmacy-related notices. This would result in $127.4 million in costs per year, or an increase of $88.2 million compared to the proposed rule. While this alternative related to notices would increase the number of notices available to beneficiaries, and therefore increase beneficiaries' opportunity to receive information regarding nondiscrimination and civil rights protections, the Department believes this alternative would neither address nor remedy the burden placed on covered entities through the 2016 Rule notice requirements. For this reason, the Department rejected this alternative.

Finally, the Department also considered not including a process for covered entities to submit a request for a religious or conscience exemption. As described in the cost section, we estimate that this policy alternative would reduce the quantified costs by $23,601. Previous Departmental rulemakings have indicated that this policy alternative could also result in providers with religious and conscience objections leaving the profession, or covered entities exiting the market. We request comment on this potential impact, including any data or studies that provide quantitative evidence that the Department's May 10, 2021 Bostock Notification ''that the Office for Civil Rights will interpret and enforce Section 1557 and Title IX's prohibitions on discrimination based on sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity''—or subsequent actions consistent with the Bostock Notification—have resulted in impacts of this nature.

We have not quantified the benefits associated with this information for the proposed rule or for these policy alternatives.

Table 4 reports the total costs of these policy alternatives in present value and annualized terms, adopting a 3% and 7% discount rate. Table 5 reports the difference between the total cost of the alternatives compared to the provisions of the proposed rule, using the same accounting methods and discount rates. All estimates are presented in millions of year-2020 dollars, using 2024 as the base year for discounting.

TABLE 4—TOTAL COST OF POLICY ALTERNATIVES CONSIDERED

[$ millions, 2020 dollars]

Accounting method discount rate	Present value		Annualized	
	3%	7%	3%	7%
Proposed Rule	$2,521.7	$2,296.4	$550.6	$560.1
Alternative 1: No Notice Provision	2,342.2	2,135.8	511.4	520.9
Alternative 2: Single Notice Provision	2,344.7	2,138.0	512.0	521.4
Alternative 3: Pharmacy-Related Notices	2,925.9	2,658.3	638.9	648.3

TABLE 5—COMPARISON OF ALTERNATIVES TO PROPOSED RULE

[$ millions, 2020 dollars]

Accounting method discount rate	Present Value		Annualized	
	3%	7%	3%	7%
Alternative 1: No Notice Provision	−$179.5	−$160.7	−$39.2	−$39.2
Alternative 2: Single Notice Provision	−177.0	−158.5	−38.6	−38.6
Alternative 3: Pharmacy-related Notices	404.1	361.8	88.2	88.2

The Department also considered whether to require covered entities to collect the self-identified race, ethnicity, primary language (spoken and written), sex, age, and disability status data for participants, beneficiaries, enrollees, and applicants in any health program or activity. The Department believes, however, that our current authorities under Section 1557, Title VI, Section 504, Title IX, and the Age Act already provide us sufficient ability to collect these data.

B. Regulatory Flexibility Act—Initial Small Entity Analysis

The Department has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act. This analysis, as well as other sections in this Regulatory Impact Analysis, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).[720] We replicate the SBA's description of this table:

''This table lists small business size standards matched to industries described in the North American Industry Classification System (NAICS), as modified by the Office of Management and Budget, effective January 1, 2017. The latest NAICS codes are referred to as NAICS 2017.

The size standards are for the most part expressed in either millions of dollars (those preceded by ''$'') or number of employees (those without the ''$''). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm.''

This initial small entity analysis adopts a finding from the 2016 Final Rule that almost all businesses under the scope of the proposed rule are small businesses. In that analysis, the total small entities numbered 254,998, which accounts for about 93% of the 275,002 covered entities under the proposed rule. The covered entities not considered small businesses include about 10% of physician practices that exceed the SBA size standard for physicians (excluding mental health specialists) (North American Industry Classification System code 62111); about 12% of pharmacies that exceed the SBA size standard for pharmacy and drug store firms (North American Industry Classification System code 44611); health insurance issuers; and local government entities.

2. Description of the Potential Impacts of the Rule on Small Entities

The Department generally considers a rule to have a significant impact on a substantial number of small entities if it has at least a 3% impact on revenue on at least 5% of small entities. We performed a threshold analysis to determine whether the proposed rule is likely to exceed these thresholds. As described earlier in this analysis, we estimate the total annualized costs of the proposed rule would be about $551 million. Dividing these total costs by the 254,998 small entities gives a cost per entity of $2,159. This cost estimate would only exceed the 3% ''significant impact'' threshold on revenue for any covered small businesses with revenue below $71,978. We tentatively conclude that very few small businesses covered by the proposed rule have revenue below $71,978, and that this number is very likely to be smaller than the 5% ''substantial number'' threshold.

As an additional consideration, we note that the costs of the proposed rule are mostly proportional to the size of the covered entity. For example, the costs associated with training, which account for more than 70% of the total costs of the proposed rule, are proportional to the number of employees receiving training. In the main analysis, we estimate an incremental impact of one (1) hour per employee trained. The opportunity cost of training each employee represents 0.05% of a full-time employee's annual labor productivity, assuming a full-time employee works 2,087 hours per year. This finding, that the cost of training represents 0.05% of the share of employees receiving training, is constant across firm size.

Because the costs of the proposed rule are small relative to the revenue of covered entities, including covered small entities, and because even the smallest affected entities would be unlikely to face a significant impact, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 13132: Federalism

As required by E.O. 13132 on Federalism, the Department has examined the effects of provisions in the

[720] U.S. Small Bus. Admin., Table of Size Standards, (last updated May 2, 2022), *https://www.sba.gov/document/support--table-size-standards.*

proposed regulation on the relationship between the Federal Government and the States. The Department has concluded that the proposed regulation has Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

The proposed regulation attempts to balance State autonomy with the necessity to create a Federal benchmark that will provide a uniform level of nondiscrimination protection across the country. The proposed regulation restricts regulatory preemption of State law to the minimum level necessary to achieve the objectives of the underlying Federal statute, Section 1557 of the ACA.

It is recognized that the States generally have laws that relate to nondiscrimination against individuals on a variety of bases. State laws continue to be enforceable, unless they prevent application of the proposed rule. The proposed rule explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation. Provisions of State law relating to nondiscrimination that are ''more stringent'' than the proposed Federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of States will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Discrimination issues in relation to health care are of national concern by virtue of the scope of interstate health commerce. The ACA's provisions reflect this position.

Section 3(d)(2) of E.O. 13132 requires that where possible, the Federal Government defer to the States to establish standards. Title I of the ACA authorized the Secretary to promulgate regulations to implement Section 1557, and we have done so accordingly.

Section 4(a) of E.O. 13132 expressly contemplates preemption when there is a conflict between exercising State and Federal authority under a Federal statute. Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rule making context when ''the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.'' The approach in this regulation is consistent with these standards in the Executive Order in superseding State authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

Section 6(b) of E.O. 13132 includes some qualitative discussion of substantial direct compliance costs that State and local governments would incur as a result of a proposed regulation. We have determined that the costs of the proposed rule would not impose substantial direct compliance costs on State or local governments. We have considered the cost burden that this proposed rule would impose on State and local health care and benefit programs, and estimate State and local government costs will be in the order of $5.7 million in the first two years of implementation. The $1.9 million represents the sum of the costs of training State workers and enforcement costs attributable to State agencies analyzed above.

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

Pursuant to E.O. 12250, the Attorney General has the responsibility to ''review . . . proposed rules . . . of the Executive agencies'' implementing nondiscrimination statutes such as Section 1557 ''in order to identify those which are inadequate, unclear or unnecessarily inconsistent.'' [721] The Attorney General has delegated that function to the Assistant Attorney General for the Civil Rights Division for purposes of reviewing and approving proposed rules, 28 CFR 0.51, and the Assistant Attorney General has reviewed and approved this proposed rule.

E. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).[722] Under the PRA, agencies are required to submit to OMB for review and approval any reporting or record-keeping requirements inherent in a proposed or final rule and are required to publish such proposed requirements for public comment. The PRA requires agencies to provide a 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to OMB for review and approval. Section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department invites public comment on its assumptions as they relate to the PRA requirements summarized in this section and explicitly invites comment from potential respondents regarding the burden estimate we ascribe to these requirements, including a discussion of respondents' basis for their computation.

The collections of information proposed by this Notice of Proposed Rulemaking relate to § 92.5 (Assurances required); § 92.7 (Designation and responsibilities of a Section 1557 Coordinator); § 92.8 (Section 1557 Policies and Procedures); § 92.9 (Training); § 92.10 (Notice of nondiscrimination); and § 92.11 (Notice of availability of language assistance services and auxiliary aids and services). Respondents to this proposed information collection would include a variety of covered entities with a health program or activity including hospitals, ambulatory surgical centers, skilled nursing facilities, and physicians' offices. For a more detailed discussion concerning the potential costs implications related to these proposed collections of information, please see the Preliminary Economic Analysis of Impacts directly below.

Proposed § 92.5 retains the assurances obligation from the 2016 and 2020 Rules for covered entities to submit an assurance of compliance to the Department. OCR has previously obtained PRA approval (OMB control # 0945–0008) for this reporting requirement via an updated HHS Form 690 (Consolidated Civil Rights Assurance Form), separate from this rulemaking. The requirement to sign and submit an assurance of compliance currently exists under Section 1557 and other civil rights regulations (Title VI, Section 504, Title IX, and the Age Act). Since the Department provides an online portal through which covered entities submit an attestation of

[721] E.O. 12250, sec. 1–202; 45 FR 72995 (Nov. 2, 1980).

[722] 44 U.S.C. 3501 *et seq.*

Assurance of Compliance, the Department has determined that this requirement imposes no additional reporting or recordkeeping requirements under the PRA.

Proposed § 92.7 requires covered entities with 15 or more employees to designate a Section 1557 Coordinator to coordinate their efforts to comply with and carry out their responsibilities under Section 1557. The burden to coordinate efforts to comply with and carry out the responsibilities under Section 1557 is estimated at an annualized burden of 10 hours per covered entity to store complaints and the associated records required under proposed § 92.8(c)(2) each year. We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $17.38 per hour. The Department estimates the number of covered entities with more than 15 employees to be approximately 15% or 41,250. We estimate the costs of retaining records related to grievances filed at all covered entities would be $14.3 million annually ($17.38 × 2 × 10 × 41,250). This estimation approach will overstate the costs if many covered entities already retain complaint information.

The burden for documenting employee training as required under proposed § 92.9(c) is the cost of covered entity staff time to (a) create training attendance forms; and (b) store the training sign-up sheet. The labor cost would include one (1) employee spending 15 minutes (0.25 hours) to create the sign-up sheet during the first year and one (1) employee spending one (1) hour collecting and storing the attendance forms during the first year and subsequent years. We estimate that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $17.38 per hour. The labor cost is $6.0 million in the first year (($17.38 × 1.25) × 275,002 covered entities). We estimate that the cost in subsequent years would be $4.8 million, which would represent an annual allotment of one (1) hour ($17.38 × 1) × 275,002 covered entities).

Proposed § 92.10 and § 92.11 require covered entities to notify the public of their nondiscrimination requirements, as well as the availability of language assistance services and auxiliary aids and services.

Proposed § 92.10 requires covered entities to provide a notice of nondiscrimination relating to its health programs or activities, to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public. To minimize burden on covered entities, the provision proposes a covered entity may combine the content of the notice required by this section with the notice required by Title VI, Section 504, Title IX, and the Age Act implementing regulations.

Proposed § 92.11 requires covered entities to notify the public of their nondiscrimination requirements, as well as availability of language assistance services and auxiliary aids and services. A covered entity must provide a notice that, at minimum, states that the covered entity provides language assistance services and auxiliary aids and services free of charge in its health programs and activities, in compliance with Section 1557. This notice must be provided to participants, beneficiaries, enrollees, and applicants of the covered entity's health program or activity, and members of the public. The notice must be provided in English and at least the most common 15 languages spoken by LEP individuals of the relevant state or states and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

Both types of notices are required (1) on an annual basis; (2) upon request; (3) at a conspicuous location on the covered entity's health program or activity website; and (4) in clear and conspicuous physical locations where the health program or activity interacts with the public.

The Department estimates the burden for responding to the proposed notice requirement would be 34 minutes and that administrative or clerical support personnel would perform these functions. Because it is difficult to determine the exact number of communications which would be required to contain the notices anticipated under the proposed rule, our cost estimates reflect a wide range of uncertainty in the cost. The Department estimates an adjusted annual primary costs total of $4.5 million, with a range of costs between $2.7 million and $25.0 million. These costs would occur in each year of the time horizon of the analysis.

TABLE 1—PROPOSED ANNUAL BURDEN OF RESPONSE IN YEAR ONE/SUBSEQUENT YEARS FOLLOWING PUBLICATION OF THE FINAL RULE

Regulation burden	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden per hours response	Total annual burden (hours) [723]
§ 92.7 Coordination Efforts	Covered entities with 15 or more employees/all covered entities.	[724] 41,250/275,002	1	316,252	[725] 10/1.25	756,252
§ 92.10 & § 92.11 Notice	All covered entities	275,002	[726] 1	275,002	34/60	93,501
Total Annual Burden Hours	.....	.....	.....	.....	.....	849,753

* The figures in this column are averages based on a range. Small entities may require fewer hours to conduct certain compliance activities, while large entities may require more hours than those provided here due to their size and complexity.

** We monetize the time spent on revising policies and procedures, depending on the extent of the revisions. For the 137,501 covered entities with less extensive revisions, we estimate two (2) total hours spent on revisions per entity. For the 137,501 covered entities with more extensive revisions, we estimate four (4) total hours spent on revision per entity.

[723] The figures in this column are averages based on a range. Small entities may require fewer hours to conduct certain compliance activities, while large entities may require more hours than those provided here due to their size and complexity.

[724] Covered entities with 15 or more employees would be required to coordinate the retention of grievance complaints for no less than three years. We have estimated that this provision would apply to approximately 41,250 covered entities. All covered entities would be required to document employee training on Section 1557. We estimated that this would apply to approximately 275,002 covered entities.

[725] We have estimated that covered entities with 15 or more employees would spend approximately 10 hours on efforts to coordinate their compliance efforts under Section 1557 as required under § 92.7. We estimate that all covered entities would spend approximately 1.25 hours documenting employee training as required under § 92.9.

[726] Because it is difficult to determine the exact number of communications which would be required to contain the notices anticipated under the proposed rule, our number of responses per respondent estimate reflects this uncertainty. The Department invites potential respondents to comment on its assumption regarding number of responses per respondent and the ultimate burden estimate we ascribe to this requirement, including a discussion of respondents' basis for their computation.

*** Because it is difficult to determine the exact number of communications which would be required to contain the notices anticipated under the proposed rule, our number of responses per respondent estimate reflects this uncertainty. The Department invites potential respondents to comment on its assumption regarding a number of responses per respondent and the ultimate burden estimate we ascribe to this requirement, including a discussion of respondents' basis for their computation.

VII. Request for Comment

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

- The financial impact of the proposed rule on the health care sector, with any detailed supporting information, facts, surveys, audits, or reports;
- Whether the application of this rule to health programs and activities that receive Federal funding, to health programs and activities of executive agencies, and to all programs and activities of executive agencies should be considered in a different manner;
- Whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and rights of people to be free from discrimination on protected bases;
- Whether covered entities that employ fewer than 15 people should be required to have a Section 1557 Coordinator and grievance procedures, and any benefits and burdens associated with such a requirement;
- Whether, and if so how, new and developing technologies can assist covered entities with their compliance obligations and enhance access to quality health care;
- The costs to provide the notice of nondiscrimination and the Notice of Availability and the impact of such notices on the utilization of language assistance services for LEP individuals and auxiliary aids and services for individuals with disabilities with any detailed supporting information, facts, surveys, audits, or reports;
- Whether the list of communications that require a Notice of Availability captures those most critical for LEP individuals and individuals with disabilities, and any detailed supporting information, facts, surveys, audits, or reports pertaining to the benefit of such notices or the related cost of their inclusion in the listed communications;
- Whether standards set pursuant to Section 510 of the Rehabilitation Act on ensuring the availability of accessible medical diagnostic equipment, should be incorporated as an enforceable standard for covered entities into the proposed rule for purposes of Section 1557;
- How best to address challenges accessing accessible medical diagnostic equipment and whether lack of access to such equipment constitutes discriminatory benefit design or network inadequacy;
- Whether Section 1557 should include a provision requiring covered entities to comply with specific accessibility standards for web content such as Section 508 standards, the WCAG 2.0 standards, the WCAG 2.1 standards, or other standards that provide equal or greater accessibility to individuals with disabilities. Additionally, OCR seeks comments on whether to adopt a safe harbor provision under which covered entities that are in compliance with established specific accessibility standards are deemed in compliance with proposed § 92.204; whether OCR should require covered entities to comply with the most recent edition of a published standard; and the timeline necessary for covered entities to come into compliance with a new standard.
- What steps the Department can take to assist covered entities in meeting their language access and effective communication responsibilities, such that these services are provided in the most efficient and effective manner for participants, beneficiaries, enrollees, and applicants of covered health programs and activities.
- Unaddressed discrimination on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, and sex characteristics), age, and disability as applied to State and Federally-facilitated Exchanges, with any detailed supporting information, facts, surveys, audits, or reports; and
- Whether covered entities seek guidance on best practices for compliance with Section 1557, and on what topics.

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 457

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, Individuals with disabilities, Medicare, Medicaid, National origin, Nondiscrimination, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 80

Administrative practice and procedure, Civil rights, Discrimination, Medicare, Nondiscrimination.

45 CFR Part 84

Administrative practice and procedure, Civil rights, Discrimination, Individuals with disabilities, Medicare, Nondiscrimination.

45 CFR Part 86

Administrative practice and procedure, Civil rights, Discrimination, Education, Medicare, Nondiscrimination, Sex discrimination.

45 CFR Part 91

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Medicare, Nondiscrimination.

45 CFR Part 92

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

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 155

Administrative practice and procedure, Advertising, Aged, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records,

Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Taxes, Technical assistance, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR parts 438, 440, 457, and 460 and 45 CFR parts 80, 84, 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 (including sexual orientation and gender identity), or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, national origin, sex (sexual orientation and gender identity), 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 (including sexual orientation and gender identity).

* * * * *

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 (including sexual orientation and gender identity). These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their individualized needs.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 6. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 7. Section 457.495 is amended by adding paragraph (e) to read as follows:

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

* * * * *

(e) Access to and delivery of services in a culturally competent manner to all beneficiaries, as described in 42 CFR 440.262.

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

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

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

■ 9. 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 (including sexual orientation and gender identity), age, mental or physical disability, or source of payment.

* * * * *

■ 10. Amend § 460.112 by revising paragraph (a) introductory text 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 (including sexual orientation and gender identity), age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

* * * * *

Title 45—Public Health

PART 80—NONDISCRIMINATION UNDER PROGRAMS RECEIVING FEDERAL ASSISTANCE THROUGH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES EFFECTUATION OF TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

■ 11. The authority citation for part 80 continues to read as follows:

Authority: Sec. 602, 78 Stat. 252; 42 U.S.C. 2000d–1.

■ 12. Amend part 1 of appendix A to part 80 by adding paragraph 155 to read as follows:

Appendix A to Part 80—Federal Financial Assistance to Which These Regulations Apply

Part 1 * * *

■ 155. Supplementary medical insurance benefits for the aged (Title XVIII, Part B, Social Security Act, 42 U.S.C. 1395j–1395w–6).

* * * * *

PART 84—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

■ 13. The authority citation for part 84 continues to read as follows:

Authority: 20 U.S.C. 1405; 29 U.S.C. 794; 42 U.S.C. 290dd–2; 21 U.S.C. 1174.

Appendix A to Part 84 [Amended]

■ 14. Amend appendix A to part 84 under subpart a by removing the third

paragraph in ''2. Federal financial assistance''.

■ 15. Revise part 92 to read as follows:

PART 92—NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

Subpart A—General Provisions

Subpart B—Nondiscrimination Provisions

Subpart C—Specific Applications to Health Programs and Activities.

Subpart D—Procedures

Authority: 42 U.S.C. 18116

Subpart A—General Provisions

§ 92.1 Purpose and applicability date.

(a) *Purpose.* The purpose of this part is to implement Section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in certain health programs and activities. Section 1557 provides that, except as otherwise provided in Title I of the ACA, an individual shall not, on the grounds prohibited 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, 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, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Department-administered health programs or activities, and Title I entities that administer health programs or activities.

(b) *Applicability date.* The regulations in this part are applicable beginning [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE], except to the extent that provisions of this part require changes to health insurance or group health plan benefit design (including covered benefits, benefit limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles); such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after [DATE ONE YEAR AFTER EFFECTIVE DATE OF FINAL RULE].

§ 92.2 Application.

(a) Except as otherwise provided in this part, this part shall apply to:

(1) Every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department;

(2) Every health program or activity administered by the Department; and

(3) Every program or activity administered by a Title I entity.

(b) The provisions of this part shall not apply to any employer with regard to its employment practices, including the provision of employee health benefits.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, 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.

§ 92.3 Relationship to other laws.

(a) Neither section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975.

(c) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Federal conscience or religious freedom laws.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at Appendix A to 28 CFR part 36 on July 26, 1991, and republished as Appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029) (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old a person is, or the number of elapsed years from the date of a person's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means a person who applies to participate in a health program or activity.

Auxiliary aids and services include, for example:

(1) Qualified interpreters on-site or through video remote interpreting (VRI)

services, as defined in 28 CFR 35.104 and 36.303(b); 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 telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology (ICT); or other effective methods of making aurally delivered information available to persons who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to persons who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Companion means a family member, friend, or associate of an individual seeking access to a service, program or activity of a covered entity, who along with such individual, is an appropriate person with whom a covered entity should communicate.

Covered entity means:

(1) A recipient of Federal financial assistance;

(2) The Department; and

(3) An entity established under Title I of the ACA.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department, or their designee(s).

Disability means, with respect to a person, a physical or mental impairment that substantially limits one or more major life activities of such person; 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 ADA, 42 U.S.C. 12102, as amended and adopted at 28 CFR 35.108.

Exchange means the same as ''Exchange'' defined in 45 CFR 155.20.

Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal Government, directly or indirectly, provides assistance or otherwise makes assistance available in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real or personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including advance payments of the premium tax credit and cost-sharing reduction payments under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health insurance coverage for payment to or on behalf of a person obtaining health insurance coverage from that entity or extended by the Department directly to such person for payment to any entity providing health insurance coverage.

Federally-facilitated Exchange means the same as ''Federally-facilitated Exchange'' defined in 45 CFR 155.20.

Health program or activity means:

(1) Any project, enterprise, venture, or undertaking to

(i) Provide or administer health-related services, health insurance coverage, or other health-related coverage;

(ii) Provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage;

(iii) Provide clinical, pharmaceutical, or medical care;

(iv) Engage in health research; or

(v) Provide health education for health care professionals or others;

(2) All of the operations of any entity principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1) of this definition, including, but not limited to, a State or local health agency, hospital, health clinic, health insurance issuer, physician's practice, pharmacy, community-based health care provider, nursing facility, residential or community-based treatment facility, or other similar entity or combination thereof.

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, but are not limited to: computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for a limited English proficient individual, and the use of qualified bilingual or multilingual staff to communicate directly with limited English proficient individuals;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into or from languages other than English; and

(3) Written notice of availability of language assistance services.

Limited English proficient individual means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. A limited English proficient individual may be competent in English for certain types of communication (*e.g.,* speaking or understanding), but still be limited English proficient for other purposes (*e.g.,* reading or writing).

Machine translation means automated translations, without the assistance of or review by a qualified human translator, that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output.

National origin includes, but is not limited to, a person's, or their ancestor's, place of origin (such as country or world region) or a person's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

OCR means the Office for Civil Rights of the Department.

Qualified bilingual/multilingual staff means a member of a covered entity's

workforce who is designated by the covered entity to provide in-language oral language assistance as part of the person's current, assigned job responsibilities and who has demonstrated to the covered entity that they are:

(1) Proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and

(2) Able to effectively, accurately, and impartially communicate directly with limited English proficient individuals in their primary languages.

Qualified individual with a disability means an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by the covered entity.

Qualified interpreter for an individual with a disability means an interpreter who, via a video remote interpreting service (VRI) or an on-site appearance, is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified interpreter for a limited English proficient individual means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language;

(2) Is able to interpret effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original oral statement; and

(3) Adheres to generally accepted interpreter ethics principles, including client confidentiality.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Qualified translator means a translator who:

(1) Has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language;

(2) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original written statement; and

(3) Adheres to generally accepted translator ethics principles, including client confidentiality.

Recipient means any State or its 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 indirectly, including any subunit, successor, assignee, or transferee of a recipient. Such term does not include any ultimate beneficiary.

Section 504 means Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means Section 1557 of the ACA (42 U.S.C. 18116).

State Exchange means an Exchange established by a State and approved by the Department pursuant to 45 CFR part 155, subpart B.

Title I entity means any entity established under Title I of the ACA, as amended, including State Exchanges and Federally-facilitated Exchanges.

Title VI means Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title VII means Title VII of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000e *et seq.*), as amended.

Title IX means Title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies must, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and 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 must, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health insurance issuer's or State's 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 section is the same as the duration of the assurances required in the Department's regulations implementing Section 504, 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.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State Exchange has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such recipient or State Exchange must take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of Section 1557 or this part, require a recipient, in its health programs and activities, or State Exchange to take remedial action with respect to:

(i) Persons who are no longer participants in the recipient's or State Exchange's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Persons who would have been participants in the health program or activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take nondiscriminatory steps, in addition to any action that is required by Section 1557 or this part, to overcome the effects of conditions that

result or resulted in limited participation in the covered entity's health programs or activities by persons on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation and responsibilities of a Section 1557 Coordinator.

(a) *Section 1557 Coordinator and designees.* A covered entity that employs fifteen or more persons must designate and authorize at least one employee, referred to herein as ''Section 1557 Coordinator,'' to coordinate the covered entity's compliance with its responsibilities under Section 1557 and this part in its health programs and activities, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or this part or alleging any action that would be prohibited by Section 1557 or this part. As appropriate, a covered entity may assign one or more designees to carry out some of these responsibilities, but the Section 1557 Coordinator must retain ultimate oversight for ensuring coordination with the covered entity's compliance with this part.

(b) *Responsibilities of a Section 1557 Coordinator.* A covered entity must ensure that, at minimum, the Section 1557 Coordinator:

(1) Receives, reviews, and processes grievances, filed under the grievance procedure as set forth in § 92.8(c);

(2) Coordinates the covered entity's recordkeeping requirements as set forth in § 92.8(c);

(3) Coordinates effective implementation of the covered entity's language access procedures as set forth in § 92.8(d);

(4) Coordinates effective implementation of the covered entity's effective communication procedures as set forth in § 92.8(e);

(5) Coordinates effective implementation of the covered entity's reasonable modification procedures as set forth in § 92.8(f); and

(6) Coordinates training of relevant employees as set forth in § 92.9 of this part, including maintaining documentation required by such section.

§ 92.8 Policies and procedures.

(a) *General requirement.* A covered entity must implement written policies and procedures in its health programs and activities that are designed to comply with the requirements of this part. The policies and procedures must include an effective date and be reasonably designed, taking into account the size, complexity, and the type of health programs or activities undertaken by a covered entity, to ensure compliance with this part.

(b) *Nondiscrimination policy.* A covered entity must implement a written policy in its health programs and activities that, at minimum, states the covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, and sex characteristics), age, or disability; that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with Section 1557 or this part; that the covered entity will provide reasonable modifications for individuals with disabilities; and provides the contact information for the Section 1557 Coordinator required by § 92.7 (if applicable).

(c) *Grievance procedures.* (1) A covered entity that employs fifteen or more persons must implement written grievance procedures in its health programs and activities that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part.

(2) A covered entity to which this paragraph applies must retain records related to grievances filed with it that allege discrimination on the basis of race, color, national origin, sex, age, or disability for no less than three (3) calendar years from the date of the filing of the grievance. The records must include the grievance; the name and contact information of the complainant (if provided by complainant); the alleged discriminatory action and alleged basis (or bases) of discrimination; the date the grievance was filed; grievance resolution; and any other pertinent information.

(3) A covered entity to which this paragraph applies must keep confidential the identity of an individual who has filed a grievance under this part except as required by law or to the extent necessary to carry out the purposes of this part, including the conduct of any investigation.

(d) *Language access procedures.* A covered entity must implement written language access procedures in its health programs and activities describing the covered entity's process for providing language assistance services to limited English proficient individuals when required under § 92.201 of this part. At a minimum, the language access procedures must include current information detailing the contact information for the Section 1557 Coordinator (if applicable); how an employee identifies whether an individual is limited English proficient; how an employee obtains the services of qualified interpreters and translators the covered entity uses to communicate with a limited English proficient individual; the names of any qualified bilingual staff members; and a list and the location of any electronic and written translated materials the covered entity has and the languages they are translated into, and the publication date.

(e) *Effective communication procedures.* A covered entity must implement written effective communication procedures in its health programs and activities describing the covered entity's process for ensuring effective communication for individuals with disabilities when required under § 92.202. At a minimum, a covered entity's effective communication procedures must include current contact information for the Section 1557 Coordinator (if applicable); how an employee obtains the services of qualified interpreters the covered entity uses to communicate with individuals with disabilities, including the names of any qualified interpreter staff members, and how to access appropriate auxiliary aids and services.

(f) *Reasonable modification procedures.* A covered entity must implement written procedures in its health programs and activities describing its process for making reasonable modifications to its policies, practices, or procedures when necessary to avoid discrimination on the basis of disability as required under § 92.205. At a minimum, the reasonable modification procedures must include contact information for the covered entity's Section 1557 Coordinator (if applicable); a description of the covered entity's process for responding to requests from individuals with disabilities for changes, exceptions, or adjustments to a rule, policy, practice, or service of the covered entity; and a process for determining whether making the modification would fundamentally alter the nature of the health program or activity, including identifying an alternative modification that does not result in a fundamental alteration to ensure the individual with a disability receives the benefits or services in question.

(g) *Combined policies and procedures.* A covered entity may combine the content of the policies and procedures required by paragraphs (b) through (f) of this section with any policies and procedures pursuant to Title VI, Section 504, Title IX, and the

Age Act if Section 1557 and the provisions in this part are clearly addressed therein.

§ 92.9 Training.

(a) A covered entity must train relevant employees of its health programs and activities on the civil rights policies and procedures required by § 92.8, as necessary and appropriate for the employees to carry out their functions within the covered entity consistent with the requirements of this part.

(b) A covered entity must provide training that meets the requirements of paragraph (a) of this section, as follows:

(1) To each relevant employee of the health program or activity as soon as possible, but no later than [DATE ONE YEAR AFTER EFFECTIVE DATE OF FINAL RULE];

(2) Thereafter, to each new relevant employee of the health program or activity within a reasonable period of time after the employee joins the covered entity's workforce; and

(3) To each relevant employee of the health program or activity whose functions are affected by a material change in the policies or procedures required by § 92.8 of this part and any other civil rights policies or procedures the covered entity has implemented within a reasonable period of time after the material change has been made.

(c) A covered entity must contemporaneously document its employees' completion of the training required by paragraphs (a) and (b) of this section in written or electronic form and maintain said documentation for no less than three (3) calendar years.

§ 92.10 Notice of nondiscrimination.

(a) A covered entity must provide a notice of nondiscrimination to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public.

(1) The notice required under this paragraph (a) must include the following information relating to its health programs and activities:

(i) The covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, and sex characteristics), age, or disability;

(ii) The covered entity provides reasonable modifications for individuals with disabilities, and appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, such as braille or large print, free of charge and in a timely manner, when such modifications, aids, and services are necessary to ensure accessibility and an equal opportunity to participate to individuals with disabilities;

(iii) The covered entity provides language assistance services, including electronic and written translated documents and oral interpretation free of charge and in a timely manner, when such services are necessary to provide meaningful access to a limited English proficient individual;

(iv) How to obtain from the covered entity the reasonable modifications, appropriate auxiliary aids and services, and language assistance services in paragraphs (a)(1)(ii) and (iii) of this section;

(v) The contact information for the covered entity's Section 1557 Coordinator designated pursuant to § 92.7 of this part (if applicable);

(vi) The availability of the covered entity's grievance procedure pursuant to § 92.8(c) of this part and how to file a grievance (if applicable);

(vii) Details on how to file a discrimination complaint with OCR in the Department; and

(viii) How to access the covered entity's website, if it has one, that provides the information required under paragraph (a)(1) of this section.

(2) The notice must be provided in a covered entity's health program or activity, as follows:

(i) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(ii) Upon request;

(iii) At a conspicuous location on the covered entity's health program or activity website, if it has one; and

(iv) In clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

(b) A covered entity may combine the content of the notice required by paragraph (a) of this section with the notices required by 45 CFR 80.6(d), 84.8, 86.9, and 91.32 if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part, so long as it includes each of the elements required by paragraph (a)(1) of this section.

§ 92.11 Notice of availability of language assistance services and auxiliary aids and services.

(a) A covered entity must provide a notice of availability of language assistance services and auxiliary aids and services that, at minimum, states that the covered entity, in its health programs or activities, provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with Section 1557 or this part, to participants, beneficiaries, enrollees, and applicants of its health program or activities, and members of the public.

(b) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by limited English proficient individuals of the relevant state or states and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(c) The notice required under paragraph (a) of this section must be provided in a covered entity's health program or activity, as follows:

(1) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(2) Upon request;

(3) At a conspicuous location on the covered entity's health program or activity website, if it has one;

(4) In clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice; and

(5) In the following electronic and written communications when these forms are provided by a covered entity:

(i) Notice of nondiscrimination required by § 92.10;

(ii) Notice of privacy practices required by 45 CFR 164.520;

(iii) Application and intake forms;

(iv) Notices of denial or termination of eligibility, benefits or services, including Explanations of Benefits, and notices of appeal and grievance rights;

(v) Communications related to a person's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant;

(vi) Communications related to a public health emergency;

(vii) Consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);

(viii) Discharge papers;

(ix) Complaint forms; and

(x) Patient and member handbooks.

(d) A covered entity shall be deemed in compliance with this section with respect to an individual if it exercises the option to:

(1) On an annual basis, provide the individual with the option to opt out of receipt of the notice required by this section in their primary language and through any appropriate auxiliary aids and services, and:

(i) Does not condition the receipt of any aid or benefit on the individual's decision to opt out;

(ii) Informs the individual that they have a right to receive the notice upon request in their primary language and through the appropriate auxiliary aids and services;

(iii) Informs the individual that opting out of receiving the notice is not a waiver of their right to receive language assistance services and any appropriate auxiliary aids and services as required by this part;

(iv) Documents, on an annual basis, that the individual has opted out of receiving the notice required by this section for that year; and

(v) Does not treat a non-response from an individual as a decision to opt out; or

(2) Document the individual's primary language and any appropriate auxiliary aids and services and:

(i) Provides all materials and communications in that individual's primary language and through any appropriate auxiliary aids and services; or

(ii) Provides the notice required by paragraph (a) of this section in that individual's primary language and through any appropriate auxiliary aids and services in all communications that are identified in paragraph (c)(5) of this section.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in Title I of the ACA, an individual must not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.

(2) Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.

(b) *Specific prohibitions on discrimination.* (1) In any health program or activity to which this part applies:

(i) A recipient and State Exchange must comply with the specific prohibitions on discrimination in the Department's implementing regulations for Title VI, Section 504, Title IX, and the Age Act, found at parts 80, 84, 86 (subparts C and D), and 91 (subpart B) of this subchapter, respectively. Where this paragraph cross-references regulatory provisions that use the term ''recipient,'' the term ''recipient or State Exchange'' shall apply in its place. Where this paragraph cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(ii) The Department, including Federally-facilitated Exchanges, must comply with specific prohibitions on discrimination in the Department's implementing regulations for Title VI, Section 504, Title IX, and the Age Act, found at parts 80, 85, 86 (subparts C and D), and 91 (subpart B) of this subchapter, respectively. Where this paragraph cross-references regulatory provisions that use the term ''a recipient,'' the term ''the Department or a Federally-facilitated Exchange'' shall apply in its place. Where this paragraph cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(2) The enumeration of specific prohibitions on discrimination in paragraph (b)(1) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for limited English proficient individuals.

(a) *General requirement.* A covered entity must take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be directly affected by its health programs and activities.

(b) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making ability of the limited English proficient individual.

(c) *Specific requirements for interpreter and translation services.* (1) When interpretation services are required under this part, a covered entity must offer a qualified interpreter in its health programs and activities.

(2) When translation services are required under this part, a covered entity must use a qualified translator in its health programs and activities.

(3) If a covered entity uses machine translation when the underlying text is critical to the rights, benefits, or meaningful access of a limited English proficient individual, when accuracy is essential, or when the source documents or materials contain complex, non-literal or technical language, the translation must be reviewed by a qualified human translator.

(d) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the limited English proficient individual; and

(2) Take into account other relevant factors, including the effectiveness of the covered entity's written language access procedures for its health programs and activities, that the covered entity has implemented pursuant to § 92.8(d).

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity must not, in its health programs and activities:

(1) Require a limited English proficient individual to provide their own interpreter, or to pay the cost of their own interpreter;

(2) Rely on an adult, not qualified as an interpreter, accompanying a limited English proficient individual to interpret or facilitate communication, except:

(i) As a temporary measure, while finding a qualified interpreter 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 limited English proficient individual immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with the accompanying adult; or

(ii) Where the limited English proficient individual specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, the request and agreement by the accompanying adult is documented, and reliance on that adult for such assistance is appropriate under the circumstances.

(3) Rely on a minor child to interpret or facilitate communication, except as a temporary measure while finding a qualified interpreter 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 limited English proficient individual immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with the minor child; or

(4) Rely on staff other than qualified interpreters, qualified translators, or qualified bilingual/multilingual staff to communicate directly with limited English proficient individuals.

(f) *Video remote interpreting services.* A covered entity that provides a qualified interpreter for a limited English proficient individual through video remote interpreting services in the covered entity's health programs and activities must provide:

(1) Real-time full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's face and the participating person's face regardless of the person's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *Audio remote interpreting services.* A covered entity that provides a qualified interpreter for a limited English proficient individual through audio remote interpreting services in the covered entity's health programs and activities must provide:

(1) Real-time audio over a dedicated high-speed, wide-bandwidth connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(2) A clear, audible transmission of voices; and

(3) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the remote interpreting services.

(h) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require a limited English proficient individual to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity must take appropriate steps to ensure that communications with individuals with disabilities (including companions with disabilities), are as effective as communications with non-disabled individuals in its health programs and activities, in accordance with the standards found at 28 CFR 35.130 and 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''covered entity'' shall apply in its place.

(b) A covered entity must provide appropriate auxiliary aids and services to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such individuals an equal opportunity to benefit from the service in question.

§ 92.203 Accessibility for buildings and facilities.

(a) No qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(b) 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 must comply with the 2010 Standards if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility must 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 must comply with the requirements for a ''public building or facility'' as defined in section 106.5 of the 2010 Standards.

(c) 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.

§ 92.204 Accessibility of information and communication technology for individuals with disabilities.

(a) A covered entity must ensure that its health programs and 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. If an action required to comply with this section would result in such an alteration or such burdens, a covered entity shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits or services of the health program or activity provided by the covered entity.

(b) A recipient or State Exchange shall ensure that its health programs and activities provided through websites and mobile applications comply with the requirements of Section 504 of the Rehabilitation Act, as interpreted consistent with Title II of the ADA (42 U.S.C. 12131 through 12165).

§ 92.205 Requirement to make reasonable modifications.

A covered entity must make reasonable modifications to policies, practices, or procedures in its health programs and activities 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 ADA Title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

(a) A covered entity must provide individuals equal access to its health programs and activities without discriminating on the basis of sex.

(b) In providing access to health programs and activities, a covered entity must not:

(1) Deny or limit health services, including those that are offered exclusively to individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

(2) Deny or limit a health care professional's ability to provide health services on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;

(3) Adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than *de minimis* harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity; or

(4) Deny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

(c) Nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual. However, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

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

(a) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

(b) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew health insurance coverage or other health-coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in health insurance coverage or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, to an individual based upon the individual's sex at birth, gender identity, or gender otherwise recorded;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care;

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex; or

(6) Have or implement benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

(c) Nothing in this section requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements, such as medical necessity requirements, in an individual case.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.208 Prohibition on sex discrimination related to marital, parental, or family status.

In determining whether an individual satisfies any policy or criterion regarding access to its health programs or activities, a covered entity must not take an individual's sex into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity must not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual in its health programs and activities on the basis of the respective race, color, national origin, sex, age, or disability of the individual and another person with whom the individual has a relationship or association.

§ 92.210 Nondiscrimination in the use of clinical algorithms in decision-making.

A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities through the use of clinical algorithms in its decision-making.

§ 92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services.

A covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age, or disability.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part.

§ 92.302 Notification of views regarding application of Federal conscience and religious freedom laws.

(a) A recipient may notify OCR of the recipient's view that it is exempt from certain provisions of this part due to the application of a Federal conscience or religious freedom law.

(b) Once OCR receives such notification from a particular recipient, OCR shall promptly consider those views in responding to any complaints or otherwise determining whether to

proceed with any investigation or enforcement activity regarding that recipient's compliance with the relevant provisions of this part. Any relevant ongoing investigation or enforcement activity regarding the recipient shall be held in abeyance until a determination has been made under paragraph (c) of this section.

(c) Based on the information provided in the notification under paragraph (a) of this section, OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part, or whether modified application of the provision is required as applied to specific contexts, procedures, or health care services, based on a Federal conscience or religious freedom law. OCR will assess whether there is a sufficiently concrete factual basis for making a determination and will apply the applicable legal standards of the relevant law. OCR will communicate its determination to the recipient.

(d) If OCR determines that a recipient is exempt from the application of certain provisions of this part or modified application of certain provisions is required as applied to specific contexts, procedures, or health care services, based on a Federal conscience or religious freedom law, that determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services.

§ 92.303 Procedures for health programs and activities conducted by recipients and State Exchanges.

(a) The procedural provisions applicable to title VI apply with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, and disability discrimination under Section 1557 or this part. These procedures are found at 45 CFR 80.6 through 80.11 and part 81 of this subchapter.

(b) The procedural provisions applicable to the Age Act apply with respect to administrative enforcement actions concerning age discrimination under Section 1557 or this part. These procedures are found at 45 CFR 91.41 through 91.50.

(c) When a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach voluntary resolution, find noncompliance with Section 1557 and initiate appropriate enforcement procedures, found at 45 CFR 80.8, including beginning the process for fund suspension or termination and taking other action authorized by law.

§ 92.304 Procedures for health programs and activities administered by the Department.

(a) This section applies to discrimination on the basis of race, color, national origin, sex, age, or disability in health programs and activities administered by the Department, including the Federally-facilitated Exchanges.

(b) The procedural provisions applicable to Section 504 at 45 CFR 85.61 through 85.62 shall apply with respect to administrative enforcement actions against the Department concerning discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 or this part. Where this section cross-references regulatory provisions that use the term ''handicap,'' the term ''race, color, national origin, sex, age, or disability'' shall apply in its place.

(c) The Department must permit access by OCR to its books, records, accounts, other sources of information, and facilities as may be pertinent to ascertain compliance with Section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or person, and the other agency, institution or person fails or refuses to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with Section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(d) The Department must not intimidate, threaten, coerce, retaliate, or otherwise discriminate against any individual or entity for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual or entity has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under Section 1557 or this part. The identity of complainants must be kept confidential by OCR in accordance with applicable Federal law.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 16. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

§ 147.104 [Amended]

■ 17. Amend § 147.104 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity)''.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 18.The authority citation for part 155 is amended to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, 18081–18083, and 18116.

§ 155.120 [Amended]

■ 19. Amend § 155.120 in paragraph (c)(1)(ii) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity)''.

§ 155.220 [Amended]

■ 20. Amend § 155.220 in paragraph (j)(2)(i) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity)''.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 21. The authority citation for part 156 is amended to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 18116, and 26 U.S.C. 36B.

§ 156.200 [Amended]

■ 22. Amend § 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity)''.

§ 156.1230 [Amended]

■ 23. Amend § 156.1230 in paragraph (b)(2) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity)''.

Dated: July 25, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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