October 3, 2022

VIA ELECTRONIC TRANSMISSION

Melanie Fontes Rainer
Director
Office for Civil Rights
Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201

Re: RIN 0945-AA17
Nondiscrimination in Health Programs and Activities

Dear Director Fontes Rainer:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. For over fifty years, we have educated, advocated and litigated to advance health equity for all without bias or barriers. We appreciate the opportunity to provide these comments on the Department of Health and Human Services' (HHS's) Office for Civil Rights (OCR) proposed rule, Nondiscrimination in Health Programs and Activities (hereinafter "2022 Proposed Rule").

Overall, we strongly support the Proposed Rule and urge HHS to finalize it as quickly as possible so that individuals across the country can benefit from its provisions. We appreciate HHS' careful and deliberative process to review prior § 1557 regulations, identify gaps, and propose solutions that recognize the importance of robust implementation and enforcement of § 1557 balanced with the concerns of all relevant stakeholders.

Our specific comments on the provisions of the 2022 Proposed Rule are as follows.

SUBPART A – GENERAL PROVISIONS

§ 92.1 Purpose and Effective Date

We support the restoration of the original language of the 2016 Final Rule to Proposed § 92.1.[1] The language of the 2016 Final Rule and the 2022 Proposed Rule[2] correctly identify that § 1557 provides individuals access to any and all rights, remedies, procedures, and legal standards available under Title VI of the Civil Rights Act of 1964 ("Title VI"), Title IX of the Education Amendments of 1972 ("Title IX") the Age Discrimination Act of 1975 ("Age Act"), or § 504 of the Rehabilitation Act of 1973 ("§ 504).

The 2020 Final Rule misconstrued the statutory language and created a piecemeal legal standard that confused and deterred enforcement.[3] We agree with HHS's interpretation in the 2022 Proposed Rule, that "Section 1557 provides an independent basis for regulation of discrimination in covered health programs and activities that is

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[1] U.S. Dept. of Health and Human Srvs., *Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg. 31376 – 31376, 31466 (May 18, 2016), https://www.govinfo.gov/content/pkg/FR-2016-05-18/pdf/2016-11458.pdf (hereinafter "2016 Final Rule").

[2] U.S. Dept. of Health and Human Srvs., *Nondiscrimination in Health and Health Education Programs or Activities, Notice of Proposed Rulemaking*, 87 Fed. Reg. 47824, 47837 (Aug. 4, 2022), https://www.govinfo.gov/content/pkg/FR-2022-08-04/pdf/2022-16217.pdf (hereinafter "2022 Proposed Rule" or "Proposed Rule").

[3] U.S. Dept. of Health and Human Srvs., *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority: Final Rule*, 85 Fed. Reg. 37160 – 37248 (June 10, 2020), https://www.govinfo.gov/content/pkg/FR-2020-06-19/pdf/2020-11758.pdf (hereinafter "2020 Final Rule").

distinct from Title VI, Title IX, the Age Act, and § 504."[4] We support language in Proposed § 92.1, and throughout the rule, that reflects this principle.

§ 92.2 Application

The 2022 Proposed Rule helps clarify who is protected under the law and what entities are subject to its requirements. Congress was clear and unequivocal in extending nondiscrimination protections to a broad swath of health programs and activities. Section 1557 prohibits discrimination in health programs and activities receiving federal financial assistance, health programs and activities administered by the executive branch, as well as entities created under the ACA, including the Marketplaces and health plans sold through the Marketplaces.[5]

Section 1557's protections are inexorably linked to broader ACA coverage requirements and other protections: "a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country."[6] This interpretation is consistent with the Supreme Court's recognition of the broader purpose of the ACA to "expand insurance coverage. . . . [and] ensure that anyone can buy insurance."[7]

The previous administration sought to exempt most federal health programs from § 1557, despite plain language of the law that says it applies to health programs "administered by an executive agency."[8] The 2020 Final Rule claimed that the only federal health programs subject to § 1557 are those established by Title I of the ACA, thereby exempting most other federal health programs from compliance.[9]

The 2022 Proposed Rule is consistent with Congress's intent in enacting § 1557. Congress intended § 1557 to build and expand upon existing civil rights laws, while providing broad protection against discrimination in health care. Moreover, Congress

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[4] 87 Fed. Reg. 47837.
[5] 42 U.S.C. § 18116(a).
[6] 81 Fed, Reg. 31379.
[7] *King v. Burwell*, 135 S. Ct. 2480, 2493 (2015).
[8] 42 U.S.C. § 18116(a).
[9] 85 Fed. Reg. 37244, *codified at* § 92.3(a)(2).

has repeatedly expressed that it intends civil rights laws to be broadly interpreted in order to effectuate their remedial purposes.[10]

Moreover, the proposed changes help implement the Biden-Harris Administration's commitment to "protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American."[11] NHeLP shares the administration's vision to "advance equity for all, including people of color and others who have been historically underserved."[12]

We strongly support the 2022 Proposed Rule which restores regulations recognizing § 1557's applicability to federal health programs like Medicaid and Medicare, the ACA's state and federal Marketplaces and the plans sold through them, as well as other commercial health plans if the insurer receives any form of federal financial assistance.

A. <u>Section 1557 broadly applies to all federal health programs and activities</u>

The plain language of § 1557, as well as the 2016 Final Rule, establish that any health "program or activity" administered by an Executive agency is subject to the law's provisions.[13] However, the 2020 Final Rule sought to exempt from § 1557 most federal health programs and agencies administering those programs, positing that Congress sought to limit application § 1557 only to federal health programs or activities created under Title I of the ACA.[14] This theory stands contrary to the statutory text, design, and intent of § 1557 and the ACA.

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

[11] Exec. Order No.14009, *Strengthening Medicaid and the Affordable Care Act*, 86 Fed. Reg. 7793-7795 (Feb. 2, 2021), https://www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02252.pdf.

[12] Exec. Order No. 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 Fed. Reg. 7009-7013 (Jan. 25, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf. *See* NHeLP's Equity Stance at https://healthlaw.org/equity-stance/.

[13] 42 U.S.C. § 18116(a); U.S. Dept. of Health and Human Srvs*., Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg. 31376, 31466 (May 18, 2016), *codified at* § 92.2(a).

[14] 85 Fed. Reg. 37244, codified at § 92.3(a)(2).

The previous administration's interpretation of § 1557 in effect changed the word "or" to "and," specifying that the law applies to health programs or activities administered by an Executive agency "and" created under Title I.[15] This reading of statute created a surplusage. If Congress had intended to limit § 1557 only to those entities created under Title I, it would not have included the clause pertaining to executive agencies.[16]

This tortured interpretation lead to a situation whereby recipients of Federal Financial Assistance (FFA) would be subject to § 1557, but the programs themselves, and the agencies administering them, would be exempt. For example, under the previous administration's interpretation, state Medicaid programs would be subject to § 1557 as recipients of FFA, but the Centers for Medicare & Medicaid Services, which administers these programs, would be exempt. Such an interpretation is not only inconsistent with the plain meaning of § 1557, but it is also inconsistent with § 504, and therefore causes significant confusion. HHS and all its components, including CMS, the Health Resources Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA), are subject to § 504's prohibition on discrimination.[17] These federal health programs and activities are likewise subject to § 1557.[18]

In the 2020 Final Rule, HHS contended that the 2016 Final Rule exceeded the bounds of the statute by describing FFA which HHS has a primary responsibility for administering, as well as FFA in which HHS "plays a role in administering.'"[19] (See further discussion on FFA in which HHS "plays a role.") Not only is this interpretation

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[15] 84 Fed. Reg. 27862.

[16] See, *e.g*., *Colautti v. Franklin*, 439 U.S. 379, 392 (1979) ("Appellants' argument . . . would make either the first or the second condition redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative."). See also, *Yates v. United States*, 135 S. Ct. 1074, 1085 (2015) (plurality opinion) (declining to read statute so as to "significantly overlap" with a distinct statute, resisting a reading that would "render superfluous an entire provision passed in proximity as part of the same Act").

[17] 29 U.S.C. § 794; 45 C.F.R. Part 85.

[18] *See also* Exec. Order No. 13166, *Improving Access to Services for Persons With Limited English Proficiency*, 65 Fed. Reg. 50121 – 50122 (Aug. 16, 2000) (requiring federal agencies to develop a plan to improve access to its federally conducted programs and activities by persons with limited English proficiency (LEP) pursuant to Title VI), https://www.govinfo.gov/content/pkg/FR-2000-08-16/pdf/00-20938.pdf.

[19] 84 Fed. Reg. 27861, citing 45 C.F.R. § 92.4.

inconsistent with § 1557, but it is inconsistent with other regulations. For example, the 2019 health care refusals rule does not limit applicability to assistance HHS has a primary responsibility for administering, but instead broadly encompasses "grants and loans of Federal funds" as part of its definition of FFA.[20]

B. HHS's § 1557 regulations should apply to all federal health programs and activities or HHS should coordinate with applicable federal agencies, programs, and activities covered by § 1557

The 2022 Proposed Rule limits its applicability to HHS health programs and only entities that receive FFA from HHS. However, § 1557 applies to programs or activities conducted by other agencies, such as the Office of Personnel Management and the Departments of Defense, Labor and Veterans Affairs. Recipients of FFA from agencies other than HHS are statutorily subject to § 1557, but are not, under the 2022 Proposed Rule, subject to implementing regulations promulgated by HHS.

Congress expressly and exclusively gave HHS the authority to promulgate government-wide regulations for the implementation of § 1557's antidiscrimination protections for all health programs and activities that receive federal financial assistance from any federal agency.[21] Yet, despite this clear statutory language, HHS has declined to extend the scope of its implementing regulations to these agencies in the 2022 Proposed Rule, the

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[20] 45 C.F.R. § 88.2.

[21] 42 U.S.C. § 18116(c) (2010). This delegation of authority specifically to HHS differs markedly from other civil rights statutes wherein Congress has directed agencies to separately develop their own implementing rules. *See* Title VI, Civil Rights Act, 42 U.S.C. § 2000d-1 (1964) ("Each federal department and agency which is empowered to extend Federal financial assistance to any program or activity…is authorized and directed to effectuate the provisions of section 2000d of this title…."); Title IX, Education Amendments, 20 U.S.C. § 1682 (1972) ("Each federal department and agency which is empowered to extend Federal financial assistance to any program or activity…is authorized and directed to effectuate the provisions of section 1681 of this title…."); Age Discrimination Act, 42 U.S.C. § 6103(a)(4) (1998) ("[A]fter the Secretary publishes final general regulations under paragraph (a)(3), the head of each Federal department or agency which extends Federal financial assistance to any program or activity…shall transmit to the Secretary and publish in the Federal Register proposed regulations to carry out the provisions of section 6102 of this title….); Rehabilitation Act, 29 U.S.C. § 794(a) (2014) ("The head of each such [Executive] agency [and United States Postal Service] shall promulgate such regulations as may be necessary to carry out the amendments to this section made by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978…..").

2016 Final Rule, and tried to further restrict the scope of § 1557 in the 2020 Final Rule to only programs and activities administered or established under Title I of the ACA. HHS previously encouraged "expeditious implementation of § 1557 by other departments" in the preamble of the 2016 Rule and OCR sent a memorandum encouraging the coordination of enforcement responsibilities to all federal agencies in November 2015.[22] HHS should now build on these prior efforts, which have not gone far enough.

HHS should coordinate with the Department of Justice (DOJ) for other departments to adopt HHS's regulations for § 1557, or urge the development and implementation of a common rule. DOJ has spearheaded common or coordinating rules and guidance to enforce Title IX and Title VI, both of which are incorporated by § 1557.[23] DOJ coordinated a common rule to implement Title IX alongside nineteen participating agencies, including the Departments of Commerce, State, Housing and Urban Development, Defense, and Veterans Affairs and the Federal Emergency Management Agency.[24] DOJ also developed regulations and guidelines to coordinate enforcement of Title VI and guidance on discrimination against persons with limited English proficiency.[25]

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[22] U.S. Dept. of Health and Human Srvs., Nondiscrimination in Health and Health Education Programs or Activities, Notice of Proposed Rulemaking, 80 Fed. Reg., 54172-54221 (Sept. 8, 2015), https://www.govinfo.gov/content/pkg/FR-2015-09-08/pdf/2015-22043.pdf; Memorandum from Jocelyn Samuels, Director, Office for Civil Rights U.S. Dept. of Health and Human Srvs., to Directors of Federal Offices for Civil Rights, *Re: Enforcement Responsibilities under Section 1557 of the Affordable Care Act* (Nov. 5, 2015), https://www.hhs.gov/sites/default/files/2015_11_04_fed_civil_rights_section_1557_memo_508.pdf.

[23] *See, e.g.*, Exec. Order No. 12250 of November 2, 1980, 45 Fed. Reg. 72995-97 (Nov. 4, 1980); *see also* Exec. Order No. 13166 of August 11, 2000, 65 Fed. Reg. 50121-22 (Aug. 16, 2000); Exec. Order No. 13160 of June 23, 2000, 65 Fed. Reg. 39775-78 (Jun. 27, 2000). (Title VI and Title IX direct each federal departments or agencies to issue rules, regulations, or orders to implement the statute but bar those rules from going into effect until approved by the President. The President delegated the authority to approve such rules under Title VI and Title IX to the Attorney General in Executive Order 12250.)

[24] *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance; Final Common Rule*, 65 Fed. Reg. 52858 – 52895 (Aug. 30, 2000), https://www.govinfo.gov/content/pkg/FR-2000-08-30/pdf/00-20916.pdf.

[25] See 28 C.F.R. § 42.401 et seq.; 28 C.F.R. § 50.3.

The need for government-wide adoption of § 1557 calls for a coordinated approach led by HHS. Absent a robust common rule or multi-agency effort, HHS should expand the scope of its existing regulations to explicitly require compliance with § 1557 by other agencies. Such an approach is consistent with the statute and would promote consistency in § 1557 implementation across agencies.

C. HHS should not exempt employer health benefit programs

The 2022 Proposed Rule includes a new provision to exempt “employment practices, including the provision of employee health benefits.”[26] We agree that, generally speaking, employment practices are outside the scope of § 1557. However, we take strong exception to exempting health benefit plans from § 1557 protections. This proposal is contrary to the plain meaning of the statute, which applies § 1557 to “any health program or activity” when any part of which receives federal financial assistance.[27]

Moreover, HHS’s proposal to exempt employee health benefit plans is contrary to a recent ruling by the 7th Circuit. In *T.S. v. Heart of CarDon*, the court found that a covered dependent under a health plan could sue under § 1557 the plan sponsor regarding an exclusion for autism treatment.[28] The court held:

> [S]ection 1557's prohibition on discrimination is not, by its own terms, limited to the discrete portion of a covered entity that receives federal financial assistance […] intentional disability discrimination in one part of CarDon's operations falls within the zone of interests protected by § 1557. The provision's purpose and text foreclose a different conclusion.[29]

HHS posits 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.”[30] We disagree. If HHS wants

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[26] Proposed § 92.2(b).

[27] 42 U.S.C. § 18116(a).

[28] *T.S. v. Heart of Cardon, LLC*, 2022 WL 3134452, 43 F.4th 737 (7th Cir. Aug. 5, 2022).

[29] *Id*. at 744.

[30] 87 Fed. Reg. 47838.

to minimize confusion among individuals who experience discrimination, it can provide clear information to complainants, and appropriate referrals to other agencies like EEOC. Moreover, HHS has no authority to limit, through rulemaking, the applicability of § 1557 contrary to the law's purpose and text.

§ 92.3 Relationship to Other Laws

We support the restoration of the language from the 2016 Final Rule in the 2022 Proposed Rule. HHS must make clear that § 1557 does not limit the rights of individuals to any right, remedy, protection, procedure, or legal standard given by Title VI, Title IX, § 504, or the Age Act. Section 1557 is a separate and distinct nondiscrimination provision that exists in tandem with other civil rights laws. Section 1557 does not limit, narrow, or restrict application of other civil rights laws. While other civil rights laws may inform the interpretation of § 1557, § 1557 stands on its own.

We support the language in Proposed 92.3, which makes reference to, but does not incorporate additional, procedures for health care refusals. Health care refusals counter evidence-based practice and medical standards of care, undermine patients' agency, and lead to worse health outcomes. Nothing in the legislative history or language of the statute itself permits exceptions to § 1557's nondiscrimination requirements. Moreover, existing statutes that allow individuals and entities to refuse to provide certain services are more than sufficient to accommodate any religious objections. Proposed § 92.3 would restore the regulatory text to the language of the 2016 Final Rule, which ensures that the only exceptions to § 1557's broad nondiscrimination mandate are specifically and explicitly contained in Title I of the ACA, including §§ 1553 and 1303. Religious freedom laws apply independently of § 1557 and should not be incorporated within the 2022 Proposed Rule.

Because of the harmful aspects of health care refusals, we do not support an extension or enlargement of the protections given by existing laws in this section or in other sections of the 2022 Final Rule. Our position is more thoroughly discussed in our response to Proposed § 92.302, below.

§ 92.4 Definitions

A. Federal Financial Assistance

The 2022 Proposed Rule restores the definition of Federal Financial Assistance (FFA) to include that in which "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."[31]

We strongly support HHS in this course correction. The 2020 Final Rule argued that only FFA administered by HHS constitutes FFA for purpose of the applicability of the rule, since premium tax credits are ultimately provided by the Internal Revenue Service (IRS).[32] The 2020 Final Rule eliminated language in the current rule saying it applies to FFA that HHS "plays a role" in administering.[33]

Under the 2020 Final Rule, the Marketplaces are subject to § 1557, covered as entities created under Title I of the ACA. However, premium tax credits and other functions, such as income, identity, and other verifications performed through the data hub might not be. The 2020 Final rule resulted in confusion and fragmentation in applicability of § 1557.

We again note that Congress gave HHS plenary authority to establish regulations for § 1557 across federal agencies; not just for HHS.[34]

We also strongly recommend that HHS explicitly require subcontractors of federal fund recipients comply with § 1557. Federal Financial Assistance does not stop being FFA once the primary recipient of federal funds cashes the payment check. It is only because that primary entity receives FFA that it will go out and build a network of secondary providers or subcontractors to undertake additional services for which the primary entity received the federal funds. Thus, the secondary recipients must also be subject to the same nondiscrimination requirements as the primary recipient or the nondiscrimination requirements may have no practical impact. An entity should not be

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[31] 87 Fed. Reg. 47912.
[32] 84 Fed. Reg. 27861.
[33] 84 Fed. Reg. 27859.
[34] 42 U.S.C. § 18116(c).

permitted to contract away its § 1557 requirements and then wipe its hands of any resulting discrimination.

The inclusion of subcontractors is particularly important given the extent to which health programs and activities contract with third parties to provide services. For example, Medicaid transportation services or personal care services are often provided under subcontracts with Medicaid managed care organizations. To exempt these providers from § 1557 simply because of their subcontractor status would render the statute's nondiscrimination protections meaningless for a significant number of services.

RECOMMENDATION: Add the following under the definition of Federal Financial Assistance:

> ***(3) A provider that contracts with a covered entity becomes a recipient of Federal financial assistance by virtue of the contract.***

B. Health Program or Activity

The 2022 Proposed Rule makes clear that health insurance companies that receive FFA are subject to § 1557. We strongly support this change. In the 2020 Final Rule, the previous administration sought to exempt most health insurance plans from § 1557, arguing that the business of health insurance is different from providing health care.[35] However, this interpretation is contrary to the plain language of § 1557, which says it applies to "any health program or activity, any part of which receives federal financial assistance."[36]

The definition of "health program or activity" promulgated by HHS in the 2016 Final Rule cited to the Civil Rights Restoration Act's ("CRRA") definition of "program or activity" as including "all of the operations of an entity [that is] principally engaged" in a covered service.[37]

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[35] 85 Fed. Reg. 37172-37173, *codified at* 45 C.F.R. § 92.3(c) "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare."

[36] 42 U.S.C. § 18116(a).

[37] 81 Fed. Reg. 31385.

HHS explained that its interpretation of “principally engaged” follows the approach of the CRRA, which it says Congress included in § 1557 via the four civil rights statutes referenced therein.[38] HHS acknowledges that under the CRRA, “the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance.”[39] HHS reasonably concluded because:

> Congress adopted a similar approach with respect to the scope of health programs and activities covered by § 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.[40]

When Congress “adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute.”[41] Congress included the same statutes covered by CRRA in § 1557, indicating that it adopted the CRRA’s broad scope. In the 2016 Final Rule, HHS explicitly noted that it was adopting an interpretation of “health program or activity” that conformed with CRRA’s broad interpretation: if any part of an entity principally engaged in healthcare receives FFA, then all of its programs and activities are subject to the discrimination prohibition.[42] The 2020 Final Rule adopted the same general interpretation, but adopted a more narrow meaning of “principally engaged in health care.”[43]

In the 2020 Final Rule, HHS supposed that providing health care “differs substantially” from providing health insurance coverage.[44] As such, HHS sought to exempt a broad swath of health insurance companies from the application of § 1557. This nonsensical result would, if fully implemented, significantly reduce the application of the law through regulation. Moreover, it is inconsistent with the plain language of § 1557 and Congress’s intent.

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[38] *Id*. at 31386.

[39] *Id*.

[40] *Id*.

[41] *Gordon v. U.S. Capitol Police*, 778 F.3d 158, 165 (D.C. Cir. 2015) (quoting *Lorillard v. Pons*, 434 U.S. 575, 581 (1978)).

[42] 81 Fed. Reg. 31432.

[43] 84 Fed. Reg. 37171.

[44] 84 Fed. Reg. 27850.

As we explained in our 2019 comments, and as HHS now recognizes, an insurer does not simply process claims.[45] Insurers design benefits and establish formularies, payment structures, and networks. Insurers conduct prior authorization and establish and evaluate other clinical coverage criteria. Insurers exercise considerable control over the health care of enrollees — deciding what providers a patient may see, what hospitals they may visit, and what treatments or medications they may receive.[46] As the 2022 Proposed Rule explains, "[i]ssuers 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."[47] We agree.

We further agree with HHS analysis that the 2020 Final Rule's exemption of health insurers is not only contrary to the design and intent of the ACA but is contrary to the plan language of § 1557 which applies to "*any* health program or activity."[48] As HHS now notes, Congress broadly applies § 1557 to health programs or activities, not just the delivery of health care services; and if Congress had intended to exempt health insurers from § 1557 requirements, it would have done so.[49] Thus, at a minimum, § 1557's applicability all of the operations of an entity principally engaged in health care, including health insurers, pharmacy benefit managers, is the only plausible reading of the CRRA and § 1557.

Without question, Congress intended the ACA and its key nondiscrimination provision, § 1557, to broadly provide protections against insurance company abuses. The very notion that HHS under the previous administration would seek to exempt insurers from

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[45] Letter from Elizabeth G. Taylor to Alex Azar II, *Re: Nondiscrimination in Health and Health Education Programs and Activities (Section 1557 NPRM)*, RIN 0945- AA11 (Aug. 12, 2019), https://healthlaw.org/resource/nhelp-comments-on-proposed-rulemaking-for-section-1557-nondiscrimination-in-health-and-health-education-programs-or-activities/.

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

[47] 87 Fed. Reg. 47845.

[48] 42 U.S.C. § 18116(a) (emphasis added).

[49] 87 Fed. Reg. 47845-47846.

nondiscrimination requirements defies rational explanation. We welcome the 2022 Proposed Rule restoration of health insurance companies in the definition of health programs or activities.

i. Group Health Plans

Although it restores definitions applying § 1557 to health insurers, the 2022 Proposed Rule would exempt certain group health plans from its requirements. As HHS explains, ”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.”[50] As the 2022 Proposed Rule notes, in this context:

> “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).
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> “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).[51]

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[50] 87 Fed. Reg. 47845.

[51] *Id*. at fn. 261.

As discussed above (see § 92.2 Application, *HHS should not exempt employer health benefit programs*), we agree that § 1557 does not apply to non-health employee benefits, such as unemployment, vacation benefits, or pre-paid legal services. However, we reject HHS proposal to exempt group health plans from § 1557 requirements. This interpretation defies the plain text and meaning of § 1557, which applies to "*any* health program or activity."[52]

Exempting group health plans from § 1557 requirements would add further confusion and fragmentation in nondiscrimination compliance and enforcement. We oppose this proposal.

ii. Pharmacy Benefit Managers

HHS invites comments on other types of health care entities it should add to the non-exhaustive list of health programs or activities that fall within its regulatory definition. We appreciate that elsewhere in the 2020 Proposed Rule, HHS discusses pharmacy benefit managers (PBMs) as among the health programs and activities that may be subject to § 1557. However, we urge HHS to expressly mention PBMs in the regulatory text as health programs or activities within the meaning of § 1557.

PBMs design prescription drug benefits, including formularies, cost sharing, utilization management, pharmacy networks, and mail order pharmacy requirements.[53] According to the NAIC, just three companies - Express Scripts, CVS Caremark (the pharmacy service segment of CVS Health and a subsidiary of the CVS drugstore chain), and OptumRx (the pharmacy service segment of UnitedHealth Group Insurance) – control approximately 89% of the market and serve about 270 million Americans.[54]

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[52] 42 U.S.C. § 18116(a) (emphasis added).

[53] See generally National Association of Insurance Commissioners (NAIC), Center for Insurance Policy and Research, Pharmacy Benefit Managers (last updated April 11, 2022), https://content.naic.org/cipr-topics/pharmacy-benefit-managers.

[54] *Id*. *See also* National Community Pharmacists Association, *NAIC Pharmacy Benefit Manager Regulatory Issues Subgroup: Pharmacist Industry Perspective* (Aug. 29, 2019, https://content.naic.org/sites/default/files/inline-files/NCPA%208-29-19.pdf (last visited Sept. 30, 2022); PCMA, *The Value of PBMs,* https://www.pcmanet.org/value-of-pbms/ (last visited Sept. 30, 2022).

Despite their growing prevalence in health care, PBMs have largely escaped regulatory oversight, operating in a netherworld between health insurers and pharmaceutical companies.[55] Section 1557 can serve as an important tool to hold PBMs accountable for discriminatory actions.

For example, in 2016, CVS Caremark, contracted to manage prescription drug benefits in Mississippi's Medicaid program, issued an amendment to its provider contracts declaring:

> Caremark has the right to exclude or terminate Provider from participation in Caremark's networks due to the fact that Provider has a practice that includes a substantial number of patients with expensive medical conditions.[56]

Sadly, no pharmacy was willing to challenge CVS Caremark for this egregious targeting of providers that serve people with high prescription drug needs, such as people living with HIV/AIDS. Although the current status of this contract amendment is unclear, HHS can help deter such discriminatory practices by expressly name PBMs among the non-exhaustive list of health programs subject to § 1557.

iii. Third party administrators

We welcome HHS's thoughtful discussion in the preamble that § 1557 protections apply broadly to activities taken by covered entities in their role as third party administrators ("TPAs").[57] Insurers often serve as TPAs, and TPAs, like insurers do more than simply process claims. TPAs often design benefits, establish formularies, payment structures, and networks. TPAs, like insurers, conduct prior authorization, and establish and evaluate other clinical coverage criteria. TPAs exercise considerable control over the health care of enrollees — deciding what providers a patient may see, what hospitals they may visit, and what treatments or medications they may receive.

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[55] See, *e.g.*, Joseph C. Bourne & Ellen M. Ahrens, *Healthcare's Invisible Giants: Pharmacy Benefit Managers*, 60 FED. LAW. 50 (May 2013); Shepherd, Joanna, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* YALE LAW & POLICY REVIEW, Vol. 38 (Jan. 1, 2019), http://dx.doi.org/10.2139/ssrn.3313828.

[56] CVS Caremark, Amendments to 2016 Caremark Provider Manual (June 6, 2016) (on file at NHeLP).

[57] 87 Fed. Reg. 47876-47877.

Yet, studies have shown that TPAs often administer plans that discriminate on prohibited bases under § 1557.[58] A TPA that administers a discriminatory plan should be liable for discrimination. This is not an unusual concept. For example, if an employer were to hire a search firm and in the description of the position said to exclude all women, minorities, and persons with disabilities, the search firm which followed that direction would be liable for discrimination. Likewise, a TPA that administers a discriminatory plan or who applies the plan terms in a discriminatory manner should be liable for that discrimination.

Section 1557 unquestionably applies to TPAs where they, or their affiliates, receive FFA.

iv. Short term, limited duration plans and excepted benefit plans

The 2022 Proposed Rule clarifies that § 1557 applies to short term, limited duration plans and excepted benefits if the issuer receives federal financial assistance.[59] These plans are exempt from ACA coverage requirements such as guaranteed issue and Essential Health Benefits (EHB), and do not meet the definition of minimum essential coverage. Although short term plans were originally designed to provide stop gap coverage, the previous administration greatly expanded their limited duration as part of its ongoing effort to sabotage the ACA.[60]

Short term plans can be inherently discriminatory.[61] They are also prone to misleading or deceptive marketing practices, which can leave highly vulnerable patients with

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[58] See, *e.g*., Anna Kirkland, et al., *Transition Coverage and Clarity in Self-Insured Corporate Health Insurance Benefit Plans*, TRANSGENDER HEALTH, 207-216 (Aug 2021), http://doi.org/10.1089/trgh.2020.0067.

[59] *See* 87 Fed. Reg. 47,875.

[60] U.S. Dept. of Labor, Dept. of Treasury, Dept. of Health and Human Srvs., *Short-Term, Limited-Duration Insurance Final Rule*, 83 Fed. Reg. 38,212-38,243 (Aug. 3, 2018), https://www.govinfo.gov/content/pkg/FR-2018-08-03/pdf/2018-16568.pdf. *See also* Center on Budget and Policy Priorities, *Sabotage Watch: Tracking Efforts to Undermine the ACA*, https://www.cbpp.org/sabotage-watch-tracking-efforts-to-undermine-the-aca (last visited Sept. 4, 2022).

[61] *See* The Leukemia & Lymphoma Society, *Short-Term Health Plans Leave Patients Vulnerable to Major Medical Bills, According to New Research* (Feb. 25, 2020), https://www.lls.org/news/short-term-health-plans-leave-patients-vulnerable-major-medical-bills-according-new-research; Dane Hansen, FSA, MAAA & Gabriela Dieguez, FSA, MAAA, Miliman

inadequate coverage or no coverage at all.[62] One major finding from a year-long investigation by the House of Representatives' Energy and Commerce Committee into the practices of insurers and brokers that offer short-term limited duration insurance is that these products discriminate against women by denying basic medical services such as pap smears, maternity, and newborn care.[63] The Committee found that many of the plans' exclusions appear designed to avoid enrolling women of child-bearing age and that all of the reviewed plans discriminated against women through gender rating, coverage exclusions, and other plan limitations.[64] These products, which are medically underwritten and include significant benefit gaps, discriminate on the basis of age, sex, and disability.

Without question, short term, limited duration plan plans and limited benefit plans are subject to § 1557 when offered by a covered entity or one of its affiliates. We welcome this clarification.

v. Medicare Part B

We strongly support OCR's proposal to treat Medicare Part B payments as federal financial assistance (FFA) and Part B providers and suppliers as recipients under § 1557, Title VI, Title IX, § 504, and the Age Act. This change in interpretation is well-supported by how the Part B program has evolved, the fact that most Part B providers are already receiving other forms of FFA, and the clear intent of the § 1557 statute. It will eliminate confusion for older adults and people with disabilities and help ensure that people with Medicare have the same protections and rights regardless of the Medicare provider they choose, the Medicare-covered service they are receiving, or whether they

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Research Report, *The impact of short-term limited-duration policy expansion on patients and the ACA individual market* (Feb. 2020), https://www.lls.org/sites/default/files/National/USA/Pdf/STLD-Impact-Report-Final-Public.pdf.

[62] Christen Linke Young and Kathleen Hannick, USC-Brookings Schaeffer Initiative for Health Policy, *Misleading marketing of short-term health plans amid COVID-19* (Mar. 24, 2020), https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/03/24/misleading-marketing-of-short-term-health-plans-amid-covid-19/?fbclid=IwAR35LAB6Gv5EB03BSDbbPLohv3xYEMJINFi76K3oXIaO4YNXEa9KAXjTAoE.

[63] U.S. House of Representatives, Energy and Commerce Committee, *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk* (June 2020), https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q-BJaURXX3/view.

[64] *Id*.

are in Original Medicare or Medicare Advantage. Bringing all Medicare providers under this rule will also help increase access to quality health care for underserved communities who face the most discrimination and barriers, as many Medicare providers serve people with other forms of insurance.

As HHS recognizes, both the original rationale for excluding Part B and changes in Medicare's payment mechanisms support HHS's revised position.[65] The statutory text of § 1557 specifically includes Part B providers and that the prior HHS policy excluding Part B providers from compliance with Title VI, § 504 and other civil rights laws was based on an antiquated definition of FFA. In the Title VI context, the exclusion of Part B providers arose soon after enactment of Medicare based on two rationales – Medicare Part B is not a "contract of insurance" and Medicare Part B providers are not directly paid by the federal government so no federal financial assistance exists. In 2022, neither of these two explanations apply, particularly to § 1557.

a. Contract of Insurance Rationale

As one rationale for the exclusion, HHS previously relied on the exclusion in Title VI's statutory language of "contracts of insurance." While we believe the original reliance on this exclusion was specious, the statutory language of § 1557 specifically ***includes*** contracts of insurance so that this rationale can no longer apply.

The legislative history of Title VI documents that the inclusion of the language "other than contracts of insurance" in Title VI was "clearly designed to assure that programs or activities financed with loans from non-Federal sources were not subject to the prohibitions of the title merely because such loans were not federally insured."[66] The legislative understanding was focused on a particular concern that Title VI – applicable to all federal financial assistance and not just health programs – should not apply to home mortgages obtained from federally insured institutions or deposits in federally insured banks. As Senator Humphrey, the Senate floor leader for the Civil Rights Act, stated:

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[65] 87 Fed. Reg. 47887-47890.

[66] *Civil Rights Issues in Health Care Delivery, A Consultation Sponsored by the United States Commission on Civil Rights*, Washington, D.C., April 15-16,1980 at 855 (hereinafter USCCR).

> The exclusion relates to, as the language says, other than a contract of insurance or guarantee. So FDIC (Federal Deposit Insurance Corporation) and all activities pertaining thereto are eliminated. The Federal Housing Administration is eliminated.[67]

The purpose of this exclusion was further reiterated by Senator Pastore, the Senate floor manager for Title VI, who said:

> The reason why we have excluded contracts of insurance or guaranty is that we do not want this section to affect, let us say, guarantees of deposits in banks. . .We do not want that section to affect FHA housing. That is precisely why the exception is put in the section.[68]

All historical accounts point to an understanding that the section was limited to banking and housing and that Title VI did apply to federally assisted health care programs in existence at the time of its passage let alone to Medicare at the time that program was enacted.[69] So the specific inclusion of "contracts of insurance" in § 1557 assuredly negated this as a rational explanation for excluding Part B providers. Thus both the statutory text of § 1557 plus Congressional intent behind Title VI support HHS's change in interpretation.

b. Direct Payment Rationale

According to an analysis of the exclusion by the U.S. Commission on Civil Rights, HHS's original decision to exclude Part B providers was in part due to the HHS Office of General Counsel determination that Medicare Part B did not constitute Federal Financial Assistance because the reimbursement was directly paid to beneficiary and is "limited to 80 percent of the reasonable costs."[70] Further, payments were made directly to beneficiaries and not to health care providers. Yet payments were only made to beneficiaries contingent on their receipt of the health servicers Medicare was intended to provide.[71]

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[67] *Id.* at 856-7, *citing* 110 Cong. Rec. 13,378 (1964).

[68] *Id.* at 857, *citing* 110 Cong. Rec. 13,345, 13.346 (1964).

[69] Hearing before Subcommittee No. 5 of the House Committee on the Judiciary, 88th Cong. 1st Sess. 1545-1546 (1963).

[70] USCCR, *supra* note 66, at 854.

[71] *Id. at 863.*

As HHS recognizes, Medicare payment policies changed and Medicare now provides direct payments, through Medicare Administrative Contractors, to providers with very few opting out of this “assignment” system. Further, any prior rationale based on the percent of reasonable costs paid by Medicare would not pass muster since other covered programs – such as Medicaid and CHIP – often do not pay providers 100% of their costs but rather lower, negotiated rates.

Further, as noted in the 2016 Final Rule, Advanced Premium Tax Credits (APTCs) and Cost Sharing Reductions (CSRs)—whether extended to the entity or to the individual for remittance – are FFA.[72] Thus the explanation that Medicare Part B payments did not constitute federal financial assistance in the 1960’s is outweighed – and indeed overridden – by the subsequent changes in program structure and reimbursement.

Thus the change in how Medicare payments are made further supports HHS’s updated interpretation of Part B payments. And now that we operate under one unified statutory provision that prohibits discrimination both on the basis of race, color and national origin as well as sex, disability and age, HHS correctly recognizes that differing standards should not continue to exist when the result is that some individuals will be protected from nondiscrimination while others will not.

c. Regulatory Impact Analysis

As noted in the Regulatory Impact Analysis for the 2016 Proposed Rule, virtually all Medicare Part B physicians are covered by § 1557 (and Title VI) as recipients of FFA.[73] This gives further support to HHS’s changed interpretation. The impact may be minor in practice but the message is loud and clear that discrimination is not permitted in any federally supported or administered health program. Further, as long as some Part B physicians remain who do not take other federal funds, HHS has a strong rationale for prohibiting the exemption that has allowed them to effectively partake in discriminatory behavior for nearly sixty years. As explained above, the initial purported reasons for allowing an exemption no longer exist and certainly cannot be allowed to persist even if

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[72] 2016 Final Rule, 81 Fed. Reg. at 31383.

[73] U.S. Dept. of Health and Human Srvs., *Nondiscrimination in Health Programs and Activities, Notice of Proposed Rulemaking* (Sept. 8, 2015), 80 Fed. Reg. 54172, 54195, https://www.govinfo.gov/content/pkg/FR-2015-09-08/pdf/2015-22043.pdf (hereinafter “2015 Proposed Rule”).

only a small number or percentage of Medicare physicians are covered. Indeed, an argument can be made that since the exemption currently only affects such a small number of Medicare Part B physicians that the weight of history is on the side of HHS's interpretation to change the exemption and explicitly prohibit **all** Medicare Part B physicians from discriminating even if the underlying assumptions of how Medicare Part B operated had not changed.

As the U.S. Commission on Civil Rights concluded in 1980, Medicare Part B payments are clearly Federal Financial Assistance and should not be excluded from Title VI as either contracts of insurance or by reason of the method of their payment.[74] The passage of time, the change in Medicare payment methods and the specific inclusion of "contracts of insurance" in § 1557 directly support HHS's change to its antiquated policy excluding Medicare Part B providers from Federal Financial Assistance.

Allowing the exemption to continue, particularly with the explicit text of § 1557 as well as the change in Medicare payment policies perpetuated the myth that providing less care to certain individuals based solely on the color of their skin or the language they speak is sometimes permissible.

As noted in a 2005 *Health Affairs* article:

> Perhaps a more troubling and longer-term consequence of [the Part B] exemption was that no federal effort was ever mounted to collect data and monitor the extent of discriminatory medical treatment. No federal testing program was developed similar to those developed to monitor discrimination in housing and employment. No public reporting requirements have been imposed as have been on lenders for home mortgage applications and approval rates by race as a result of the Home Mortgage Disclosure Act of 1975. Yet, despite repeated calls for such data and the overwhelming role that federal dollars play in financing medical services, the void persists. There has never been a lack of regulatory authority to require such collection and reporting; it has always been a lack of political will.[75] (citations omitted)

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[74] *Id.,* at 863.

[75] David Barton Smith, *Racial And Ethnic Health Disparities And The Unfinished Civil Rights Agenda,* HEALTH AFF., 24, no.2 (2005):317-324.

HHS's own 2016 Regulatory Impact Analysis concluded that very few healthcare providers only accept Medicare Part B and thus would be exempt.[76] The current proposal to change the policy of HHS to explicitly **include** Medicare Part B providers as covered by § 1557 would affect a small number of individuals but provide a long-needed correction to ameliorate a harmful, discriminatory policy enacted in a foregone era when it was wrongly regarded as legitimate for healthcare providers to exclude certain patients based on the color of their skin or the language they speak. In the 21st century, and with the specific statutory inclusion of contracts of insurance in § 1557, that longstanding policy no longer has any legs to stand on. Indeed, bringing Medicare Part B providers into compliance with all other federally funded healthcare providers is critical for this Department to correct a wrong and recognize how far this nation has come in seeking to address discrimination.

vi. Affiliates, subsidiaries, or related corporate entities

Health programs and activities are provided by an increasingly complex web of separate, but related corporate entities, which some have tried to exploit to evade compliance with § 1557's nondiscrimination protections.

Consider the following example. Plaintiffs in a pending case, *Garfoil, et al., v. Aetna*, brought a § 1557 claim of LGBTQ discrimination by the company in its role as a TPA for a self-insured employer plan. In its reply, Aetna declared:

> Aetna Inc. does not provide insurance coverage and is not a proper party to this action. All references to "Aetna" hereafter shall be construed to mean Aetna Life Insurance Company or related entities that provide health insurance coverage in the State of New York, unless otherwise specified.[77]

The company appears to be setting up a defense distinguishing between their separate entities' lines of business. Aetna is one of the largest health insurers in the country, providing health coverage to thirty-nine million people.[78]

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[76] 2015 Proposed Rule, *supra* note 73.

[77] Def. Amended Answer to Plaintiff's Amended Complaint, *Goidel, et al., v. Aetna, Inc*., No. 1:21-cv-07619 (S.D.N.Y. Feb. 11, 2022).

[78] See Aetna Facts, https://www.aetna.com/about-us/aetna-facts-and-subsidiaries/aetna-facts.html (last visited Sept. 6, 2022).

In another recent example, CVS Caremark argued that § 1557 did not apply to its PBM operations because "'operations' are functions that an agency performs; entities themselves are not operations and thus operations cannot include the work of other separate legal entities."[79] The court then endeavored to untangle the complex corporate structure of the CVS parent company, PBM operations, pharmacy and related LLC entities.[80] The court rejected CVS' argument that the case should be dismissed because it was not a covered entity, concluding that

> [t]o ignore the overall interrelationship among the entities which, in the case at bar, design and implement the allegedly discriminatory program and permit the CVS interrelated entities to escape responsibility would exalt form over substance and impair the effectiveness of the anti-discrimination provision of the ACA.[81]

In the 2016 Final Rule, HHS announced that it will engage in case-by-case inquiry, "rely[ing] on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities," and "examin[ing] whether the purpose of the legal separation is a subterfuge for discrimination--that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage."[82]

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[79] *Doe One v. CVS Pharmacy, Inc*., No. 18-cv-01031-EMC, slip op.at 9 (N.D. Cal., Aug. 5, 2022).

[80] "CVS Health Corporation's 2020 Form 10-K filing with the United States Securities Commission, Defendant CVS Pharmacy, Inc. is a direct subsidiary of CVS Health Corporation. CVS Pharmacy, Inc. in turn, is a parent company of the other Pharmacy Defendants and the PBM Defendants. See SAC ¶ 135 (establishing that CVS Pharmacy, Inc. is a parent company of Defendant Caremark PCS Health, L.L.C.); (explaining that CVS Pharmacy, Inc. is the indirect parent company of the two PBM Defendants and Garfield Beach CVS, and that CVS Pharmacy operates CVS retail pharmacy locations, directly and through subsidiaries, throughout the country)." *Id*. at 3 (internal citations omitted).

[81] *Id*. at 9.

[82] 81 Fed. Reg. 31433. The "civil rights" cases to which OCR refers incorporate several different tests. For example, in determining whether an affiliated group of corporations should be aggregated in calculating employer size for purposes of determining whether certain federal civil rights laws apply, the Seventh Circuit has identified three circumstances where aggregation would be appropriate: (1) when the traditional conditions for piercing the corporate veil are present; (2) when an enterprise has split up into separate corporations "for the express purpose of avoiding liability under the discrimination laws"; or (3) when "the parent company . . . directed

The 2016 Final Rule takes the right approach. However, the 2022 Proposed Rule provides little explanation of how OCR will "pierce the corporate veil" when determining whether an entity is covered under § 1557. Accordingly, we urge HHS to provide greater clarity on when liability under § 1557 extends across affiliated companies.

C. Auxiliary Aids and Services

We support HHS's proposal to incorporate the definition of "auxiliary aids and services" from the Americans with Disabilities Act (ADA).[83] We suggest one modification to the definition to clarify that staff who step in to interpret for an individual with a disability have clear qualifications to do so. It is still all too common for an entity to claim that outside interpreting is not necessary because they believe that current staff can provide effective communication. We also recommend that the text clarify that "similar services and actions" are available for all individuals with disabilities, not just for deaf and hard of hearing individuals and blind and low vision individuals referenced in subsections (1) and (2).

RECOMMENDATION: Amend the definition of auxiliary aids and services to delete "and" at the end of subsection (3), add new subsection (4) and renumber subsection (4) as subsection (5) as follows:

> *(4)* ***Staff acting as interpreters: A covered entity must not use staff who use sign language or another communication modality[84] to act as***

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the discriminatory act, practice, or policy." *Papa v. Katy Indus*., 166 F.3d 937, 940-41 (7th Cir. 1999). Other circuits (including the Second, Fifth, Sixth, and Eighth Circuits) have adopted a four-part test originally developed by the National Labor Relations Board for determining whether to consolidate separate corporations as a civil rights plaintiffs' employer. *Cook v. Arrowsmith Shelburne, Inc.*, 69 F.3d 1235, 1240-41 (2d Cir. 1995). This test requires a showing of "(1) interrelation of operations, (2) centralized control of labor relations, (3) common management, and (4) common ownership or financial control." *Cook* at 1240. In our view, the former, three-part test most aptly applies to § 1557 enforcement.

[83] 28 C.F.R. § 35.104; 28 C.F.R. § 36.303(b).

[84] Throughout these comments we use the term "communication modality" to refer to a variety of ways interpreters may communicate with clients, including, for example, cued speech transliteration or oral transliteration. We recognize that American Sign Language (ASL) interpreters, for example, are interpreting from one language to another, while other types of interpreters may be transliterating spoken English into a method of communication that

interpreters and relay information to individuals with disabilities unless a) they meet the definition of a qualified interpreter for an individual with a disability found within this section and b) meet the unique needs of the individual requesting the accommodation; and

(5) Other similar services and actions ***that support people with disabilities in effective communication.***

D. Companion

We appreciate the inclusion of the definition of the term "companion," and HHS's explanation that a companion may include a "family member, friend, or associate of an individual. . ." who is "an appropriate person with whom a covered entity should communicate." We note, however, that the determination of who is appropriate must lie with the individual with a disability (or their designated decision-maker pursuant to state law), and not with the provider. Deferring to the individual with a disability to determine who is their companion or appropriate person to communicate with is critically important as providers communicating directly to non-designated companions may not only violate privacy laws, but undermines the autonomy of people with disabilities. We suggest that HHS add language to clarify that the determination of who is "appropriate" lies with the individual, not with the provider.

We also recommend that HHS add a requirement that a "companion" of an LEP individual who needs language services must also be provided meaningful access including access to qualified interpreters and translated materials. The 2022 Proposed Rule requires covered entities to take appropriate steps to ensure effective communication for companions of individuals with disabilities. We believe the same should be afforded to LEP individuals, particularly LEP parents/guardians of English-speaking minors/incapacitated adults and also family members, friends or associates of LEP individuals who are appropriate persons with whom a covered entity should communicate. This could include individuals who participate in decision-making with the LEP individual or need to understand the information for caregiving and other related reasons.

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facilitates understanding for an individual with a disability. In these cases, we are using the term communication modality in instances where the interpreter is not interpreting between two different languages.

E. Qualified Interpreter for an Individual with a Disability

We support HHS's proposal to incorporate the definition of "qualified interpreter for a person with a disability" from the ADA.[85] However, we suggest closer alignment for the definitions related to qualified interpreter for a limited English proficient individual (LEP) and qualified interpreter for an individual with a disability. We believe all interpreters should demonstrate proficiency in either communicating and understanding both English and a non-English language (including American Sign Language (ASL), other sign languages) or proficiency in another communication modality (such as cued speech or oral transliteration). Additionally, all interpreters should interpret "without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original statement and [also] adhere. . . to generally accepted interpreter ethics principles including client confidentiality."[86] Alignment of the standards should decrease confusion for covered entities, increase the likelihood that all interpretation will be provided with sufficient standards and meet the requirements, and increase the likelihood that all people who need interpretation or access to auxiliary aids and services will have the access to care they need.

RECOMMENDATION: Amend the definition of qualified interpreter for an individual with a disability as follows:

> Qualified interpreter for an individual with a disability means an interpreter who, via a video remote interpreting service (VRI) or an on-site appearance**:**
>
> ***(1) has demonstrated proficiency in communicating in, and understanding:***
> - ***(i) both English and a non-English language (including American Sign Language, other sign languages); or***
> - ***(ii) another communication modality (such as cued-language transliterators or oral transliteration);[87]***

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[85] 28 C.F.R. §§ 35.104, 36.104.

[86] 84 Fed. Reg. 47913.

[87] We note that not all interpreters for people with disabilities are interpreting between English and another language. In some cases, they are acting as transliterators, interpreting from one communication modality into English. Another example would be Certified Deaf Interpreters, who are individuals who are deaf or hard of hearing and may be interpreting between an individual who is deaf and uses a unique version on ASL or foreign, or home signs unfamiliar to

(2) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary ***or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original statement; and***

(3) adheres to generally accepted interpreter ethics principles including client confidentiality.

Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

F. Qualified Interpreter for an Individual with limited English proficiency

We strongly support the requirements for and definition of a "qualified" interpreter. The correlation between oral interpretation by trained professional interpreters and improved access to quality of care is well-documented.[88] We do, however, recommend an addition to the definition as well as a clarification.

With regard to the addition, we suggest that an interpreter who is nationally certified should automatically meet the definition of qualified. While we acknowledge that competency to interpret does not necessarily require formal certification, as HHS recognizes in the LEP guidance, "it may be helpful."[89] As we have advanced since 2000 to have more formalized competency-based assessments for healthcare interpreters,

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the medical interpreter (See, *e.g.*, Registry of Interpreters for the Deaf, *Certified Deaf Interpreter* (CDI), https://rid.org/rid-certification-overview/available-certification/cdi-certification/.)

[88] For example, patients with LEP who are provided with interpreters make more outpatient visits, receive and fill more prescriptions, and report a high level of satisfaction with their care. Additionally, these patients do not differ from their English proficient counterparts in test costs or receipt of intravenous hydration and have outcomes among those with diabetes that are superior or comparable to those of English proficient patients. Truda S. Bell et al., *Interventions to Improve Uptake of Breast Screening in Inner City Cardiff General Practices with Ethnic Minority Lists*, 4 ETHNIC HEALTH 277 (1999); Thomas M. Tocher & Eric Larson, *Quality of Diabetes Care for Non-English-Speaking Patients: A Comparative Study*, 168 WESTERN J. OF MEDICINE 504 (1998); David Kuo & Mark J. Fagan, *Satisfaction with Methods of Spanish Interpretation in an Ambulatory Care Clinic*, 14 J. OF GENERAL INTERNAL MEDICINE 547 (1999); L.R. Marcos, *Effects of Interpreters on the Evaluation of Psychopathology in Non-English-Speaking Patients*,136 AMERICAN J. OF PSYCHIATRY 171 (1979).

[89] 68 Fed. Reg. 47316 (Aug. 8, 2003), http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf (hereinafter "HHS LEP Guidance").

we believe it is now appropriate for HHS to recognize that a nationally certified interpreter will meet the 2022 Proposed Rule's definition of a "qualified" interpreter. Only in situations when an interpreter is not certified would a covered entity then have to assess whether the interpreter is competent and qualified. This will both encourage the use of certified interpreters, and also assist providers who may have little to no ability or knowledge about how to assess an interpreter's knowledge, skills and abilities refrain from trying to make the determination about whether an interpreter is qualified. Best practices for ensuring competent oral interpretation may be taken from the leading certification entity for health care interpreters, the Certification Commission for Healthcare Interpreters (CCHI).[90] CCHI and the National Board of Certification for Medical Interpreters,[91] another certification entity, both use standards established by the National Council on Interpreting in Health Care.[92]

We also recommend that HHS recognize sometimes interpreters may not interpret to/from English. Particularly with regard to individuals who speak less frequently encountered languages or certain dialects or indigenous languages for which interpreters may not be readily available, "relay" interpreters may be needed. For example, if an individual with limited English proficiency speaks Mixteco or another indigenous language, a covered entity may not be able to readily access an interpreter from English to/from Mixteco but may need to utilize one interpreter to interpret English to/from Spanish and a second interpreter who can interpret from Spanish to/from Mixteco. In these situations, the "qualified" interpreter would need to be proficient in both languages (Spanish, Mixteco) but not necessarily English. We recommend HHS amend the definition of "qualified interpreter for individual with limited English proficiency" to address this situation. We also suggest that HHS include discussion of the potential need to use relay interpreters in the Preamble to the final rule. This may also occur for individuals who have a disability who are also LEP who may, for example, need an interpreter for a non-English based sign language.

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[90] Certification Commission for Healthcare Interpreters, https://cchicertification.org/.

[91] The National Board of Certification for Medical Interpreters, https://www.certifiedmedicalinterpreters.org/.

[92] National Council on Interpreting in Health Care, *National Standards of Practice for Interpreters in Health Care*, https://www.ncihc.org/assets/z2021Images/NCIHC%20National%20Standards%20of%20Practice.pdf.

<u>RECOMMENDATION:</u> Amend the definition of "qualified interpreter for a limited English proficient individual" parts (1) and (2) to read as follows:

(1) Has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language ***or in the two languages which are relevant for the interpreting the interpreter is providing;***
(2) Is able to interpret effectively, accurately, and impartially to and from such language(s) and English ***(or a second language which is not 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

G. Linguistic Variants

We also propose that HHS add a definition to address the concept of linguistic variants as a distinct form of a language used by people from a specific community or region. Many languages spoken in the U.S. are actually language families with many distinct linguistic variants (also known as "dialects") that may be used in the same country of origin, but are frequently not mutually intelligible. For example, Mixteco is an Indigenous language from Southern Mexico that is widely spoken among California's farmworkers. Mixteco is a complex tonal language with over 50 distinct variants that vary based on the speaker's community of origin, and people who speak different variants often cannot communicate effectively with each other.[93] The difference between Mixteco variants can be compared to the difference between Spanish and Portuguese.

It is also important to note that the term "dialect" is falling out of favor by linguists and discouraged by advocates. It is frequently used inaccurately and often used purposefully to diminish the value of languages. For example, Indigenous languages of Latin America are often inaccurately called "dialects," implying that they are a dialect of Spanish. Given that they were spoken in Latin America for thousands of years before the arrival of Spanish-speaking Europeans, this term is inaccurate and offensive. "Variants" or "variations" is the preferred and accurate term when talking about a

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[93] *See e.g.,* Bax, Anna, *Language Ideology, Linguistic Differentiation, and Language Maintenance in the California Mixtec Diaspora* (Sept. 2020), https://escholarship.org/uc/item/7867c7n0/.

language family that contains variations (such as variants of Mixteco) and “language” when identifying a language, such as Mixteco.

H. Relevant Employee

As we discuss in § 92.9 below, we recommend HHS add a definition of “relevant employee” from the preamble into the regulatory text itself. That can be done in the definitions section or in § 92.9. Without a definition in the regulatory text, covered entities may not refer back to the Preamble and understand that “relevant employee” refers not only to public contact positions but also to individuals developing and determining the budgets for the entities’ policies, procedures, and compliance which is a critical aspect of the definition.

Recommendations: Add a definition of relevant employee to § 92.4 as follows:

> ***Relevant employee* means any relevant health program and activity staff involved in client and patient interactions, as well as those involved with drafting, approving, and funding policies and procedures for compliance with this part.**

§ 92.5 Assurances Provided

We strongly support requiring applicants and entities to submit assurances of compliance with § 1557. In addition, as detailed below, we recommend requiring data collection (see discussion below) as part of the assurances and to demonstrate compliance with § 1557. This provision as it is important that federal funding applications and agreements include reference to the requirement to comply with § 1557 itself as well as the implementing regulations of this part. We suggest HHS consider additional ways to ensure that covered entities comply with the statute and regulations. For example, HHS grant applications could request information about how the entity would meet the requirements of this part, particularly with regards to how it will provide language assistance services and auxiliary aids and services, what the entity’s communication access plan includes, and whether the proposed budget includes the funding needed to meet the identified needs.

Applicants and grantees should be required to provide specific information in their proposals and funding in their budgets to comply. This may include funding for interpreters or translated materials, auxiliary aids and services and other communication mechanisms. Applications could also require entities to provide information about their policies and procedures for assisting individuals with LEP and disabilities. Along with assurances to comply with § 1557 and this part, specific requirements in HHS applications (including the accompanying budgets) -- and the agency's analysis thereof in the contracting process -- would help ensure inclusion of the policies, procedures and funding essential to meet the requirements of this part. This should become an automatic step in HHS's review of applications and consideration in grant agreements.

§ 92.7 Designation and responsibilities of a Section 1557 Coordinator

We appreciate the provision that covered entities must have a designated § 1557 coordinator. OCR requested comment on whether this provision should apply to entities with fewer than fifteen employees and we recommend that the answer be yes. Even in smaller covered entities, it is essential that someone is responsible for coordinating implementation of § 1557 including developing the required policies and procedures, ensuring relevant employees are trained, receiving and addressing grievances, and informing individuals of their rights when they interact with the covered entity. There will not be a one-size-fits-all solution and a smaller entity might not have to have a full time coordinator. However, we believe it is critical that all covered entities have a designated person to ensure compliance with the law and these regulations.

Individuals may choose to get care from smaller providers for a variety of reasons and these decisions should not impact their right to not face discrimination. For example, entities providing long-term services and supports (LTSS) to older adults and people with disabilities are often small in nature. These are often preferred by older adults and people with disabilities because the services they provide are often daily and intimate. While preventing discrimination is critical in all health care settings, having a coordinator to ensure that § 1557 is implemented is essential to daily life for someone who resides at a covered entity or receives home- and community-based services.

If HHS maintains the fifteen employee threshold, we suggest that HHS clarify how entities count employees. That is, we recommend that part-time employees count towards this amount. Further, entities should not be able to utilize significant numbers of contractors to avoid meeting the employee minimum. For some entities, using subcontractors—such as interpreters for less frequently encountered languages—

makes sense. But we are concerned that some entities may adopt policies to utilize more subcontractors if they do not count as employees and thus help an entity remain under a threshold. This possibility also supports our recommendation to eliminate the minimum number of employees and instead recognize that the expectations for having a coordinator (and having grievance procedures discussed later) may vary based on the size of the entity but that all entities have a responsibility to comply with § 1557, have a designated employee responsible for doing so, and have methods by which individuals who allege discrimination by a covered entity have a mechanism for obtaining redress directly from the covered entity.

§ 92.8 Policies and procedures

We strongly support the provisions requiring covered entities to adopt § 1557 policies and procedures and to ensure their employees are trained on them. We agree with HHS that both employees in "public contact" positions and those who make decisions about these policies and procedures should receive training so they understand the requirements of § 1557. We hope that such policies and procedures will ensure that covered entities are better able to meet the requirements of § 1557.

A. Communication Access Plans

However, we are unclear, whether the required policies and procedures include advance planning to identify what services might be required. In particular, we recommend that HHS require covered entities to develop a communications access plan that addresses both language access and accessibility for people with disabilities (including people with disabilities who are LEP). For example, the 2022 Proposed Rule discusses the need for "language access procedures" which seems to be more the "nuts-and-bolts" of how to schedule an interpreter, how to identify whether an individual is LEP, etc.[94] But there is no requirement that a covered entity think **in advance** of what types of language services it may need. But without gathering data about the LEP population in its service area, an entity may not be able to develop effective policies and procedures. Covered entities should also plan in advance, and prepare, to ensure they can meet the communication needs of people with disabilities, including the provision of appropriate auxiliary aids and services, such as qualified interpreters.

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[94] 87 Fed. Reg. 47847.

HHS has long recognized the benefit of creating a language access plan. HHS's 2003 LEP Guidance included elements of an effective language access plan.[95] As noted in the 2016 § 1557 NPRM's preamble, many organizations already develop such plans based on the model described in HHS LEP Guidance.[96] For example, Medicare Part A providers must already develop of a language access plan.[97] In its 2016 rulemaking, HHS noted that the time needed to develop a language access plan was approximately three hours initially and only one hour for review in subsequent years.[98] This time commitment seems well balanced weighed against the critical need for LEP individuals to have effective communication and the time wasted when language services are not available and care is delayed, denied or negligently provided.

Requiring a broader communication access plan (not just a language access plan) would help ensure that covered entities understand the scope of the populations they serve, the prevalence of specific language groups in their service areas, the likelihood of those language groups coming in contact with or eligible to be served by the program, activity or service, the communication and accessibility needs of people with disabilities in the service area, the nature and importance of the communications provided and the cost and resources available. Depending on an entity's size and scope, advance planning need not be exhaustive, but is used to balance meaningful access with the obligations on the entity. The size and scope of the plan may vary depending on whether the covered entity is a small provider or a larger entity. Further, HHS can better monitor compliance of entities that have a language access plan.

Specifically, a number of aspects of a language access plan mentioned in HHS's 2003 LEP Guidance, but not in the 2022 Proposed Rule include:

- how to respond to LEP callers;
- how to respond to written communications from LEP persons;
- how to respond to LEP individuals who have in-person contact with recipient staff; and
- how to ensure competency of interpreters and translation services.[99]

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[95] HHS LEP Guidance, 68 Fed. Reg. 47316.

[96] See, *e.g*., 80 Fed. Reg. 54183.

[97] 81 Fed. Reg. 31454.

[98] *Id.*

[99] HHS LEP Guidance, 68 Fed. Reg. 47320.

The Centers for Medicare & Medicaid Services has developed a reference guide for developing language access plans.[100]

We recommend OCR either modify § 92.8 to clarify that additional steps to develop a communication access plan are necessary before developing relevant policies and procedures. In the alternative, OCR could add a new provision requiring the development of a communication access plan prior to the development of policies and procedures.

As we noted above, it is particularly important for covered entities to be proactive in their thinking and planning when developing policies and procedures to enforce § 1557. Such policies and procedures are all ways to elevate internal knowledge and proactive implementation of civil rights among covered entities and thereby alleviate the burden on placed on individual patients when patient complaints are the primary means of triggering enforcement. For example, during the COVID-19 pandemic, poor planning, and inadequate policies and procedures failed many people seeking health services, including people with disabilities. At the beginning of the pandemic, the “no visitation” policies adopted almost universally among in-patient facilities provides a timely and urgent reminder of why broader and deeper awareness of civil rights is needed among healthcare entities. Family members, friends, and paid caregivers who provide the personal care assistance needed by people with a range of disabilities were treated as simple “visitors” and turned away by security personnel, nurses, and other healthcare providers. The result placed people with disabilities at grave risk of having their communication and health care needs ignored or misunderstood, left unable to equally benefit from health care services, or being forced to undergo additional invasive procedures such as restraint or the insertion of a feeding tube.

The COVID-19 public health emergency only highlighted how hospitals and health care facilities of various sizes have long failed to fully integrate and operationalize civil rights laws, leaving people with disabilities, their advocates, and their family members with few or no timely options to obtain the effective communication and policy modifications necessary for good health outcomes.

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[100] Ctrs. for Medicare and Medicaid Servs., *Guide to Developing a Language Access Plan* (rev. July 2022), https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.

Violations of civil rights laws occur not only due to intentional ill will. They can happen because of ignorance, neglect, and administrative indifference, as noted in the findings of the Americans with Disabilities Act of 1990. In the arena of health care, covered entities tend to prioritize the establishment of policies, procedures, and a “chain of command” for meeting regulations, viewing civil rights regulations as an inconvenient add-on obligation. Fortunately, there is growing awareness across all segments of the healthcare system, from providers to insurers to public health, that technical adherence to regulations does not automatically achieve **equitable** health care and more needs to be done to eliminate embedded systemic and implicit bias.[101]

Further, as OCR notes in the 2003 LEP Guidance, “effective plans set clear goals and establish management accountability.” We believe both goals and accountability are essential to ensuring effective implementation of § 1557.

The American Medical Associations’ Commission to End Health Care Disparities, comprised of over seventy-five member organizations, has also recognized the need to undertake an assessment of LEP populations:

> . . .identifying the best ways to use interpreters in an organizational context requires a formal assessment of the needs of the populations served and the resources available in the organization, including service and staff capacity to meet patient communication needs. Hence, an ambulatory practice with the majority of physicians and staff who are native Spanish speaking may not require trained interpreters for its Spanish speaking patient populations (though health care organizations should note that even native speakers of languages other than English may not have sufficient proficiency to communicate in that language during a medical encounter). (citation omitted) An otherwise similar ambulatory practice with few native speakers might identify substantial need for trained interpreters or clinicians who are proficient to conduct medical encounters in languages other than English. The only way to ensure these needs are being met, and that disparities are not being introduced, is to collect data and proactively track the care provided to patients with LEP.[102]

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[101] Rohan Khazanch et al., *Racism, Civil Rights Law, And The Equitable Allocation Of Scarce COVID-19 Treatments*, HEALTH AFF. FOREFRONT (Feb. 10, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220208.453850/.

[102] Regenstein M, Andres E, Wynia MK, for the Commission to End Health Care Disparities. *Promoting appropriate use of physicians’ non-English language skills in clinical care: A white*

Similarly, the National Quality Forum (NQF) recommends “strategic planning” to meet the needs of a diverse patient population. An entities’ strategic plan should be developed with the participation of consumers, community, and staff who can convey the needs and concerns of all communities and all parts of the organization affected. This is necessarily different than policies and procedures which, as NQF recognizes, “can provide a supportive base for meeting the needs of a diverse population.”[103] NQF also recommends implementing language access planning. It notes that

> [a] language services coordinator should be a staff member who is designated to coordinate all language service activities, and this coordinator should be familiar with the service needs of the LEP population, the resources available in the community, and potential partners and funding sources for meeting the identified needs.[104]

B. <u>Competency of Interpreters, Translators, Readers and Bilingual/Multilingual staff</u>

We would also recommend a requirement that covered entities develop policies and procedures to assess the competency of anyone who will interpret or translate but particularly regarding bilingual/multilingual staff. These could include language proficiency assessments or other methods of ensuring that staff are indeed qualified to provide services whether for an individual with LEP or an individual with a disability. Such individuals must demonstrate that they are competent to provide services in a non-English language (including ASL or other sign languages; or another communication modality such as cued speech transliteration or oral transliteration). If staff are acting as interpreters to relay information, they should meet the qualifications

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paper of the Commission to End Health Care Disparities with recommendations for policymakers, organizations and clinicians. American Medical Association, Chicago IL 2013, https://www.immigrationresearch.org/system/files/Promoting_Appropriate_Use_of_Physicians_Non-English_Language_Skills_in_Clinical_Care.pdf.

[103] National Quality Forum (NQF), *A Comprehensive Framework and Preferred Practices for Measuring and Reporting Cultural Competency: A Consensus Report* (2009), at 43, https://www.qualityforum.org/Publications/2009/04/A_Comprehensive_Framework_and_Preferred_Practices_for_Measuring_and_Reporting_Cultural_Competency.aspx.

[104] *Id.* at 44.

of the term “qualified interpreter for an individual with a disability” within the meaning of § 92.4.

C. Updating Policies and Procedures

Finally, the provision on policies and procedures does not mention an expectation for ongoing evaluation or updating of an entity’s policies and procedures. As HHS notes in the 2003 LEP Guidance, “effective plans set clear goals and establish management accountability.”[105] We believe both goals and accountability are essential to ensuring effective implementation of § 1557.

We also recommend adding “effective” in § 92.8(d) to mirror the language already included in § 92.8(e).

RECOMMENDATION: Amend § 92.8(a) to add at the end:

> ***The entity must review and as needed, update, its policies and procedures at least once per year.***

RECOMMENDATION: Amend § 92.8(d) and (e) as follows:

> (d) ***Effective l***~~*L*~~*anguage access procedures*. A covered entity must ***develop a language access plan*** and***, based on that plan,*** implement written ***effective*** language access procedures . . .
> (e) *Effective communication procedures.* A covered entity must ***develop a communication access plan and based on that plan,*** implement written effective. . .

RECOMMENDATION: Amend § 92.8 to add new subsection (h) as follows:

> ***(h) A covered entity’s language access procedures and effective communication procedures must include how the entity will assess individuals to determine if they are a qualified interpreter, qualified translator, qualified reader or qualified bilingual/multilingual staff person.***

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[105] HHS LEP Guidance, 68 Fed. Reg. 47321.

D. Grievance Procedures

Similar to our recommendation raised in § 92.7 about requiring a § 1557 coordinator at entities with fewer than fifteen employees, we also recommend that HHS require these entities to develop and operate grievance procedures. It is unclear to us why an entity with fourteen employees would be exempt while an entity with fifteen would not. This actually may cause some covered entities to limit the size of their staff or utilize non-employee contractors to avoid having to develop grievance procedures. Any individual who suffers discrimination by a covered entity should have a mechanism for having the issue addressed in the first instance by the covered entity. While we recognize the availability of other enforcement mechanisms, the time and resources needed to get resolution of an administrative or judicial complaint likely would defer many individuals from pursuing those remedies. As previously noted about the coordinator, the grievance procedures for a smaller entity need not be as extensive or involve as many staff or resources as one would expect from a larger entity. However, we believe that individuals who receive care from smaller entities should have a mechanism to raise concerns directly with the entity and to have the concerns addressed in a "prompt and equitable" manner. HHS could develop a model grievance policy for smaller entities to help them comply with a requirement.

§ 92.9 Training

We support this provision that requires training on civil rights policies and procedures for all relevant employees. We agree it is critical that not only individuals in "public contact" positions understand civil rights policies and procedures but also that those who make decisions about these policies and procedures understand the requirements of § 1557 We note that the preamble to the 2022 Proposed Rule includes a definition of "relevant employees, but the regulatory text does not.[106] We believe that this definition should be added to the regulatory text in § 92.4 or in § 92.9.

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[106] 87 Fed. Reg. 47850.

<u>Recommendations</u>: Add a definition of relevant employee to § 92.4 as follows:

> ***<u>Relevant employee</u> means any relevant health program and activity staff involved in client and patient interactions, as well as those involved with drafting, approving, and funding policies and procedures for compliance with this part.***
>
> **OR** Add a definition of relevant employee to § 92.9 as follows:
>
> ***(d) Relevant employee means any relevant health program and activity staff involved in client and patient interactions, as well as those involved with drafting, approving, and funding policies and procedures for compliance with this part.***

Training for relevant employees should include teaching on how to implement the organization's policies and procedures, when and where notices should be provided, and how to provide effective communication for LEP individuals and persons with disabilities. For example, with respect to policies involving LEP individuals, a covered entity should require training on how to best work with interpreters, particularly the type of interpreters the covered entity uses (*e.g.* in-person, telephonic, video).
As noted by the American Medical Association's Commission to End Health Care Disparities:

> All employees should receive training so that they understand when an interpreter should be used, how interpreter services can be accessed, what the language services options are (*e.g.*, in-person, telephone, video, translation services) and documentation requirements for quality, utilization, billing and internal reporting purposes.[107]

The same types of training policies should be adopted with respect to qualified interpreters and readers for people with disabilities.

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[107] Regenstein, *supra* note 102*.*

§ 92.10 Notice of nondiscrimination

We strongly support the requirements related to a notice of nondiscrimination. When this provision was removed in prior rulemaking, many individuals never received information about their rights; did not know how to access interpreters, auxiliary aids and services; and did not know how to file a complaint or a grievance.

A notice that clearly explains the breadth of § 1557 rights, and provides information on how to practically obtain those rights, including contact information for the entity's § 1557 coordinator, is particularly important for people with disabilities because disabilities can be acquired at any point in life by individuals who may have little or no preexisting knowledge of disability rights.

In addition to the current requirements, we recommend HHS include in the notice requirement that any entity receiving a religious exemption under proposed § 92.302 include the existence and scope of such exemption in its required notices. It would be misleading and inaccurate to require entities to tell participants and beneficiaries and the public generally that the entity does not discriminate if the entity does in fact discriminate in certain circumstances and has been granted permission to do so.

§ 92.11 Notice of availability of language assistance services and auxiliary aids and services

We strongly support HHS's proposal to require notice of the availability of language assistance services and auxiliary aids and services for people with disabilities in health programs and activities. People with disabilities and people with limited English proficiency have improved access to health services when they are able to access appropriate auxiliary aids and services. Notice that clearly explains the breadth of § 1557 rights, and provides information on how to practically access those protections, including contact information for the entity's § 1557 coordinator, is particularly important for people with disabilities and people with LEP.

Access to accessible, nondiscriminatory care is further complicated by the lack of knowledge of disability-related responsibilities under nondiscrimination laws by providers. For example, a recent study found that more than a third of U.S. physicians do not know their legal requirements under the ADA, and more than 70% did not know they share responsibility with patients for determining reasonable accommodations to ensure access to care, and 20% incorrectly identified who pays for those accommodations.[108] As a result, it is critical that people with disabilities receive notice of their rights to auxiliary aids and services and, relatedly, for covered entities to develop procedures to ensure these notices are brought to the attention of people who have disabilities that can interfere with typical ways of reading and understanding the content of the notice. Covered entities must notify enrollees, beneficiaries and other participants of their right to request effective communication and auxiliary aids and services, and detailed information about disability function and accommodation needs in electronic health records. Including such information in electronic health records would decrease the burden of asking repeatedly for the same accommodations and provide information readily to providers about the needs of individuals they are serving.

We also appreciate that the Proposed Rule properly makes clear that these services required under paragraph (a) must be provided free of charge.

Our experience during the COVID pandemic has reinforced the need to require a notice such as the one proposed here. In a complaint we filed with the HHS Office for Civil Rights, we documented the widespread failures of states and other covered entities to provide notice and language services.[109] We also call to your attention two recent reports about the lack of language access during COVID. For example, a majority of Latinx respondents who have not been vaccinated said they would not take the vaccine or are not sure; of these, 67% reported Spanish as their primary language at home; about half of respondents think misinformation about the vaccine is a serious problem, with Facebook and messaging apps the top reported platforms for misinformation.[110]

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[108] Lisa I. Iezzoni et al., *U.S. Physicians' Knowledge About the Americans with Disabilities Act and Accommodations of Patients with Disability,* HEALTH AFF. (Jan. 2022), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01136.

[109] NHeLP, *Administrative Complaint: Discriminatory Provision of COVID-19 services to persons with limited English proficiency* (April 2021) (hereinafter COVID Complaint), https://healthlaw.org/news/civil-rights-complaint-filed-over-discriminatory-provision-of-covid-19-services-to-persons-with-limited-english-proficiency/.

[110] VotoLatino, *LADL: Nationwide Poll on COVID Vaccine* (Apr. 21, 2021), https://votolatino.org/media/press-releases/polloncovid/. See also see, *e.g*., Jorge A. Rodriguez et al., *Differences in the Use of Telephone and Video Telemedicine Visits During the COVID-19 Pandemic*, 27 AM. J. OF MANAGED CARE (Jan. 14, 2021), https://bit.ly/3vtWmlg.

A. Notice Procedures

While we support the notice requirements on auxiliary aids and services in Proposed § 92.11, we ask that HHS address the following recommendations to ensure people have meaningful access to communication services:

- Covered entities must ask members/beneficiaries whether they have language access needs or communication disabilities and record their needed services and auxiliary aid(s) or service(s) in the electronic health record so that they can consistently receive effective communication from the covered entity.
- HHS should clarify that if an individual requests that all written communications be rendered in alternative formats or in a non-English language, then all future communications, including but not limited to the finite list of significant communications in subsection § 92.11(c)(5), should be provided in the requested format or language.
- HHS should work on developing template notices in plain language formats that will make information accessible to people with intellectual and developmental disabilities.

We believe the intent of the notice is similar to the “tagline” requirement from the 2016 Final Rule and that the notice would be short although recognizing the addition of information of the availability of auxiliary aids and services.

For the English version of the notice, we recommend OCR require that information be provided in at least 18-point font to ensure readability. We also recommend HHS require that covered entities that operate across multiple states aggregate the top fifteen languages in each state and not be permitted to only provide the notice in the top 15 languages across all of the states an entity operates in.

For example, using data HHS Office for Civil Rights developed for states in 2016, in Illinois, the top fifteen languages spoken by limited English proficient individuals are Spanish, Polish, Chinese, Korean, Tagalog, Arabic, Russian, Guajarati, Urdu, Vietnamese, Italian, Hindi, French, Greek and German.[111] In California, the top fifteen

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[111] HHS OCR, *Resource for Entities Covered by Section 1557 of the Affordable Care Act, Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 states, the District of Columbia, and the U.S. Territories*, https://www.hhs.gov/sites/default/files/resources-for-covered-entities-top-15-languages-list.pdf.

languages were Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Persian (Farsi), Russian, Japanese, Arabic, Panjabi, Khmer, Hmong, Hindi and Thai.[112] Similarly, in New Jersey, the languages were Spanish, Chinese, Korean, Portuguese, Gujarati, Polish, Italian, Arabic, Tagalog, Russian, French Creole, Hindi, Vietnamese, French and Urdu. If a covered entity can use only the top fifteen languages amongst all three states, it would not have a notice in Khmer, the 12th language in California but differing from the 15th overall language by only 3,000 individuals. It also would fail to cover Urdu, the 9th most used language in Illinois, or Hmong, the 13th most used language in California.[113]

If a covered entity operates in multiple states, it could either include more than fifteen languages on one document used in multiple states or could have different documents in each state. We do recommend HHS require a minimum font size so that if an entity chooses to have more than fifteen languages that it must still use at least a twelve-point font or the usefulness of the statement will be diminished if the font is too small to recognize.

Additionally, the notice should be positioned toward the front of the written or electronic publications. HHS's proposed list of written and electronic communications includes comprehensive documents such as patient handbooks and other multi-page publications. If the notice is placed at the end of these publications, individuals with limited English proficiency will be less likely to see the notice and know that they can get language assistance services. For example, during past ACA enrollment periods, assistors working with consumers in the Marketplaces reported numerous cases where individuals with LEP did not see taglines on critical Marketplace notices pertaining to their rights. Consumers received multi-page notices requesting additional documentation or other actions, but individuals often did not see the taglines located at the end of the notice. As a result, they discarded their notices, resulting in termination of coverage and other negative outcomes. This experience underscores the importance of both the content of the notice and location within a communication.

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[112] *Id.*

[113] NHeLP analysis of data included in HHS OCR *Resource for Entities Covered by Section 1557 of the Affordable Care Act, Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 states, the District of Columbia, and the U.S. Territories, supra* note 111.

B. Model Notices

Finally, we suggest that HHS develop targeted notices that will address a variety of common situations. We have significant concerns about the use of a "one-size-fits-all" type of notice. The type of electronic or written communication this notice accompanies will have different impact. For example, a communication notifying an individual or denial or termination of eligibility will require a different response from the recipient than a document about a public health emergency or a patient/member handbook. For the notice of availability of language assistance services and auxiliary aids and services to be effective, it must be tailored to the type of response needed by the reader and include specific information about the next steps an individual should take.

C. Types of Electronic and Written Communication Covered

With regards to the list of electronic and written communications that must include the notice of availability in Proposed § 92.11(c)(5), we recommend HHS add electronic health/medical records. More and more covered entities utilize and rely on electronic health/medical records and online portals to communicate with individuals, for scheduling, for posting test results, and communicating with health care providers. Thus it is essential that these systems are accessible to both individuals with LEP and individuals with disabilities. At a minimum, the electronic communications should include the notice of availability to inform individuals how to get assistance in accessing these portals/systems.

We also suggest that HHS specify that documents related to the No Surprises Act, such as the Surprise Billing Protection Form, must include the notice. While we appreciate and support the inclusion of notices related to denial or termination of services, we believe that providing information **prior** to a medical procedure or operation that is specifically intended to inform an individual about protections from unexpected medical bills is also critically important. Providing this notice could hopefully avoid some of the issues that can arise after a procedure. While this could be covered under Proposed § 92.11(c)(5)(vii), some covered entities may not consider the No Surprises Act notice of the same type as informed consent for a procedure because the No Surprises Act notice is more about payment than consent. We suggest HHS add language to (vii) to include information related to the No Surprises Act as it should occur hand-in-hand with consent for a medical procedure.

SUBPART B – NONDISCRIMINATION PROVISIONS

§ 92.101 Discrimination prohibited

A. Proposed § 92.101(a)

We are concerned that individuals with limited English proficiency are sometimes denied access to health care programs or healthcare not because of their language but because of incorrect and discriminatory assumptions that the person's limited English proficiency may indicate the person's immigration status. We documented many problems due to a lack of language services in a complaint we filed with the HHS Office for Civil Rights about the lack of language services during the pandemic. As just two examples:

- A Spanish-speaking individual called a Los Angeles county hospital call center for Covid-19 vaccine scheduling. Call center staff demanded the individual's immigration status and insurance information, and would not schedule a vaccine appointment until the individual shared their immigration status.[114]

- In Northern California, a Spanish speaker was deterred from getting the Covid-19 vaccine at a hospital after being asked for their Social Security number.[115]

The intersectional issues that come into play with language, race/color, and immigration status can often lead to individuals with LEP facing significant discrimination in addition to being denied access to programs and care for which they are entitled and eligible.

We also support the prohibition of discrimination on the basis of disability. As just a few examples of discrimination faced by people with disabilities:

- A hospice care provider refused to provide a deaf son who was the primary caretaker of his mother, the care recipient, with an interpreter. This prevented him from communicating about his mother's end-of-life care with the care team.[116]

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[114] COVID Complaint, *supra* note 109, at 7.

[115] *Id.* at 7-8.

[116] Br. of Amici Curiae Disability Organizations at 13-14, *Cummings v. Premier Rehab Keller*, No. 20-219 (Aug. 30, 2021) (available from NHeLP).

- A hospital failed to provide a deaf person in need of emergency medical care with any accommodation. This left the deaf patient to resort to handwritten notes as the only means of communication, a much less effective way to communicate one's needs.[117]

- A deaf woman with a high-risk pregnancy asked for an interpreter during childbirth. Hospital staff dismissed her request, leading her to suffer embarrassment and humiliation as she gave birth.[118]

B. <u>Proposed § 92.101(a)(2)</u>

We appreciate the inclusion of a definition of "discrimination on the basis of sex" in this section. We agree that, consistent with the Supreme Court's interpretation of other civil rights laws that prohibit sex discrimination, it is appropriate to explicitly prohibit discrimination based on sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. However, HHS should further clarify that the scope of sex discrimination protections include pregnancy status including termination of pregnancy. HHS should also clarify how § 1557 includes protections based upon more than one basis – *e.g.*, intersectional protections.

i. Prohibited LGBTQI+ sex discrimination

As noted in the preamble to the Proposed Rule, Lesbian, Gay, Bisexual, Transgender, Queer, Intersex plus (LGBTQI+) people face both health disparities and barriers to health care. The National Academies of Sciences, Engineering, and Medicine reports that discrimination against Sexual and Gender Diverse[119] persons in obtaining health insurance, and in the terms of insurance coverage, has long been a barrier to accessing health care, which has contributed to significant health inequalities.[120] LGBTQI people

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[117] *Id.* at 14.
[118] *Id.*
[119] We use the term "Gender Diverse" as an umbrella term to refer to people whose gender identity, including their gender expression, is at odds with what is perceived as being the gender norm in a particular context at a particular point in time, including people who identify as Gender Fluid, Gender Expansive, or Genderqueer.
[120] Nat'l Academies of Sciences, Engineering, and Med., *Understanding the Well-Being of LGBTQI+ Populations* (2020), https://nap.nationalacademies.org/catalog/25877/understanding-the-well-being-of-lgbtqi-populations.

report poorer health overall and are at increased risk of numerous health conditions such as sexually transmitted infections, HIV, substance abuse, and mental health conditions including suicidality. They also are more likely than heterosexual individuals to acquire a disability at a young age.

Much of this can be attributed to well-documented discrimination. According to a 2010 report addressing health care discrimination against LGBT people and people living with HIV, more than half of all respondents reported at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.[121] The same report found that many members of the LGBT community have a "high degree of anticipation and belief that they w[ill] face discriminatory care" which ultimately causes many people to not seek care.[122]

Years later, the situation has not much improved. The Department's Healthy People 2020 initiative recognized that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[123] This surfaces in a wide variety of contexts, including physical and mental health care services.[124] In a study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[125] They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access. A recent systematic literature review conducted by Cornell University "found robust evidence that

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[121] Lambda Legal, *When Health Care Isn't Caring* 9-10 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

[122] *Id.* at 6.

[123] U.S. Dept. of Health and Human Srvs., Off. Disease Prev. & Health Prom., *Healthy People 2020: Lesbian, Gay, Bisexual, and Transgender Health*, https://wayback.archive-it.org/5774/20220413203148/https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health (last visited Sep. 12, 2022).

[124] Ryan Thoreson, Hum. Rights Watch, *"All We Want is Equality": Religious Exemptions and Discrimination against LGBT People in the United States* 13 (2018), https://www.hrw.org/sites/default/files/report_pdf/lgbt0218_web_1.pdf.

[125] Ning Hsieh & Matt Ruther, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care*, 36 HEALTH AFF. 1786 (2017).

discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people."[126]

These problems persist in 2022. Data in a new report from the Center for American Progress "reveal that LGBTQI+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers, underscoring the importance of strengthening nondiscrimination protections through § 1557 of the Affordable Care Act."[127] Key findings from the report include:

- Twenty-three percent of LGBTQI+ respondents, including 27 percent of LGBTQI+ respondents of color, reported that, in the past year, they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers;
- Fifteen percent of LGBQ respondents, including 23 percent of LGBQ respondents of color, reported experiencing some form of care refusal by a doctor or other health care provider in the year prior;
- Overall, thirty-two percent of Transgender or Non-Binary respondents, including forty six percent of Transgender or Non-Binary respondents of color, reported that they experienced at least one kind of care refusal by a health care provider in the past year;
- Fifty-five percent of Intersex respondents reported that, in the past year, a health care provider refused to see them because of their sex characteristics or intersex variation;

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[126] What We Know Project, Cornell University, *What Does the Scholarly Research Say about the Effects of Discrimination on the Health of LGBT People* (online literature review), 2019, https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/.

[127] Caroline Medina & Lindsay Mahowald, *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities*, Center for American Progress (Sep. 8, 2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities.

- Thirty percent of Transgender or Non-Binary respondents, including forty seven percent of Transgender or Non-Binary respondents of color, reported experiencing one form of denial by a health insurance company in the past year;

- Twenty-eight percent of Transgender or Non-Binary respondents, including twenty nine percent of Transgender or Non-Binary respondents of color, reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior; and

- Twenty-two percent of Transgender or Non-Binary respondents, including thirty percent of Transgender or Non-Binary respondents of color, reported that a health insurance company denied them coverage for gender-affirming surgery in the year prior.[128]

Compounding this discrimination is the fact that education about LGBQ patients is deeply inadequate in health professional curricula in the U.S.[129] Medical education about Transgender, Gender Diverse, and Intersex patients is even worse.[130] The refusal to substantially invest in education bleeds into every facet of our health system, because while providers can treat conditions, they cannot treat what they do not know. These institutional and systemic gaps often force LGBTQI+ patients to educate their providers about their identities and health care needs, and why those health needs are important.[131]

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[128] *Id.*

[129] *See, e.g.,* Rachel D. Cohen, *Medical Students Push for More LGBT Health Training to Address Disparities, NAT'L PUB. RADIO,* Jan. 20, 2019, https://www.npr.org/sections/health-shots/2019/01/20/683216767/medical-students-push-for-more-lgbt-health-training-to-address-disparities;Kathleen A. Bonvicini, *LGBT Healthcare Disparities: What Progress Have We Made?*, 100 PATIENT EDUC. & COUNS. 2357 (2017) (lack of training for medical and nursing students); Nicole Copti et al., *Lesbian, Gay, Bisexual, and Transgender Inclusion in Physical Therapy: Advocating for Cultural Competency in Physical Therapist Education Across the United States*, 30 J. PHYS. THERAPY EDUC. 11 (2016), Markus P. Bidell, *Mind Our Professional Gaps: Competent Lesbian, Gay, Bisexual, and Transgender Mental Health Services*, 31 COUNS. PSYCHOLOGY REV. 67 (2016).

[130] *Id.*; *see also*, Samuel B. Dubin et al., *Transgender Health Care: Improving Medical Students' and Residents' Training and Awareness* (May 21, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5967378/.

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

Thus, clear protections prohibiting sex discrimination in health care are vital to protecting the health and wellbeing of LGBTQI+ people. Explicit protection against discrimination on the basis of sexual orientation and gender identity is not only consistent with the Supreme Court's recent decision in *Bostock*, but it is also crucial to protecting the rights of the LGBTQI+ community and addressing health inequities.

Further, we strongly support the proposed broad regulatory language to prohibit discrimination on the basis of sex that specifically includes discrimination on the basis of sex stereotypes, sex characteristics, including intersex traits, sexual orientation, and gender identity and the provision's impact on older adults. LGBTQ+ older adults experience pronounced health disparities and higher poverty rates compared to their heterosexual and cisgender peers due in large part to historical and ongoing discrimination.

There is significant evidence that discrimination in health care contributes to these disparities: LGBTQ+ older adults may be denied care or provided inadequate care, or they may be afraid to seek necessary care for fear of mistreatment. For example, many LGBTQ+ elders and their loved ones' experience discrimination in long-term care facilities ranging from verbal and physical harassment, to being denied basic care such as a shower, to visiting restrictions and isolation, to being improperly discharged or refused admission. Transgender older adults in particular experience discrimination in coverage of medically necessary care related to gender transition, as well as in coverage of lifesaving tests and treatments associated with one gender. Transgender people of color face significant barriers to health care access, from denials of gender affirming care to medical abuse.

ii. Prohibited discrimination based on sexual orientation

We support HHS's explicit inclusion of discrimination related to sexual orientation in its definition of sex discrimination. Consistent with the Supreme Court's recent decision in *Bostock v. Clayton County*, the rule prohibits discrimination based on sexual orientation.[132] This protection is important to address disparities and barriers for Lesbian, Gay, Bisexual, and Queer people. We support this provision of the rule since it

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Report-Dec17.pdf at 96. Twenty-four percent of Transgender participants reported having to teach the provider about Transgender people in order to receive care.

[132] 590 U.S. __, 140 S.Ct. 1731 (2020).

will ensure, for example, that a long-term care facility could not implement a policy to only place Gay men in single rooms, when it places heterosexual men in shared rooms.[133]

Unfortunately, too many individuals still suffer discrimination based on sexual orientation. Examples of covered entities discriminating on the basis of **sexual orientation**. Many of these stories are also relevant to discrimination on the basis of association, discrimination based on religious or moral grounds, and discrimination based on marital, parental or family status. These include:

- In 2008, hospital staff at a public hospital in Florida denied a dying woman's partner of 21 years access to her for eight hours as she suffered and advanced to brain death. During this time, her partner repeatedly asked to see her, explaining the relevant relationships and even having the power of attorney faxed to the hospital. The hospital staff did not allow her and the couple's children to see their dying loved one until the patient's sister arrived, with a hospital staff member telling them they were in "an anti-gay city and state" and would not be acknowledged as a family.[134]

- A married lesbian couple in Michigan were told by a pediatrician that he would be their child's doctor when the baby was born. Six days after the birth, they brought their baby to the office but were informed by a different doctor that their chosen pediatrician would not meet with them after having "prayed on it."[135]

- An Alabama pediatrician discharged a 13-year old boy from her "Christian practice" after he came out as gay.[136]

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[133] *See, e.g.,* Justice in Aging et al., *LGBT Older Adults in Long-Term Care Facilities* at 6 (2015 ed.), https://justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf; *cf.* ECRI, Ask HRC: *When Patients Object to Transgender Roommates*, Health System Risk Man. Guidance, Jan. 22, 2018, https://www.ecri.org/components/HRC/Pages/AskHRC012218.aspx.

[134] Br. of GLBTQ Legal Advocates & Defenders and 27 Other LGBTQ Advocacy Groups as Amici Curiae at 18-19, *Fulton v. City of Philadelphia*, No. 19-123 (Aug. 20, 2020), https://www.supremecourt.gov/DocketPDF/19/19-123/150770/20200820135738835_GLAD%20Amicus%20Br.%20-%20Fulton%20v%20%20Philadelphia%20-%20MASTER%20-TO%20FILE.PDF.

[135] *Id.* at 20.

[136] *Id.* at 19.

- A lesbian woman in Alabama was refused assisted reproductive services because of the doctors' religious beliefs. When she asked the office for a referral to another provider, the practice told her, "I don't know who else would want to treat you."[137]

- A doctor in Alabama told a hospital patient he was "sorry for that" when the patient said that he was gay and had a partner. When he was later hospitalized again, an uninvited person came to his room to pray over him and left a pamphlet that stated "you must repent and be filled with the holy spirit or you will go to hell."[138]
- A nursing home transferred a 79-year old gay man who did not suffer from dementia to a "memory ward" due to complaints from other residents and their families about his presence. After being confined with residents with severe cognitive impairments such as Alzheimer's disease, he eventually hanged himself.[139] **While this story is not directly applicable to PACE (programs of all-inclusive care for the elderly), the preamble relies on statistics regarding discrimination against LGBTQI+ nursing home residents as support for the proposed amendments to 42 CFR 460.98(b)(3) and 460.112(a) that would explicitly prohibit discrimination on the basis of sexual orientation or gender identity in PACE. (Fed. Reg. 47894).

- A gay man who sought care for a severe infection at a New York City hospital "was treated roughly physically and emotionally." A hospital aide used a gay slur to refer to him on more than one occasion. At one point during his hospital stay, this patient was dragged down the hall in an office chair and ended up falling. The patient was left on the floor, convulsing and urinating on himself. When a

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[137] *Id.*

[138] *Id.* at 21.

[139] Br. of Amici Curiae Services and Advocacy for Gay, Lesbian, Bisexual and Transgender Elders and American Society on Aging at 18-19, *Masterpiece Cakeshop v. Colorado Civil Rights Commission*, No. 16-111 (Oct. 26, 2017). https://www.scotusblog.com/wp-content/uploads/2017/11/16-111bsac-sage-asa.pdf.

> nurse ran toward him yelling that she could lose her job, “[t]he health aide responded, ‘this junky faggot isn’t going to make you lose your job.’”[140]

iii. Prohibited discrimination based on gender identity

We appreciate that, consistent with *Bostock*, Proposed § 92.101(a)(2) also prohibits discrimination based on gender identity. This protection will go a long way toward addressing discrimination and barriers faced by Transgender, Non-Binary, Gender Non-Conforming, Gender Expansive, and other Gender Diverse individuals. It will ensure, for example, that a pharmacist may not ask a Non-Binary person questions about their genitals before administering a vaccination, when the pharmacist does not ask those questions of cisgender people.[141]

It is worth noting that the legal landscape is rapidly changing with regard to legal recognition of Non-Binary identities. Approximately half of states in the U.S. legally recognize Non-Binary gender markers for legal identity records, and the federal government recognizes Non-Binary gender markers for U.S. passports.[142] Medicare has removed gender markers from member cards altogether and some state Medicaid agencies are following suit.[143] Yet the deep inconsistency in policies around gender markers and sex-data requirements at the federal and state levels creates barriers for Transgender and Gender Diverse people who may have variations in gender data on their identity documents. This can flag inconsistencies in verification data to determine eligibility for health insurance coverage, such as Medicaid. Implementation of § 1557

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[140] Br. of Amici Curiae Lambda Legal Defense Fund et al. at 10, *Masterpiece Cakeshop v. Colorado Civil Rights Commission*, No. 16-111 (Oct. 30, 2017). https://www.scotusblog.com/wp-content/uploads/2017/11/16-111_bsac-lambda-legal-et-al.pdf.

[141] *See, e.g.,* Beyond Binary Legal & Harvard Law School LGBTQ+ Advocacy Clinic, *How Federal Agencies Can Ensure Nondiscrimination and Advance Equity for Nonbinary and Gender Nonconforming People* 2-3 (2022), https://static1.squarespace.com/static/5e5821d555aa43474493b45d/t/62fa7e56157431683154d0cf/1660583511170/2022.08.15+federal+agencies+nonbinary+equity.pdf.

[142] Movement Advancement Project, *Identity Document Laws and Policies* (last updated Aug. 23, 2022), https://www.lgbtmap.org/equality-maps/identity_document_laws.

[143] Ctrs. Medicare & Medicaid Servs., *New Medicare Card Project* (2017). https://www.rds.cms.hhs.gov/sites/default/files/webfiles/documents/rds-new-medicare-card-project-webinar-slide-deck.pdf.; Dep’t Health Care Servs., *Beneficiary Identification Card Change* (2021), https://www.dhcs.ca.gov/services/medi-cal/eligibility/letters/Documents/I21-20.pdf.

should ensure that health insurance programs improve sex-related questions on health insurance applications and forms to ensure everyone can access coverage. Sex-related data should be requested if such data is necessary. While collecting data on sexual orientation, gender identity, and sex characteristics is important for purposes of advancing health equity, requiring such data should not prevent anyone, especially historically marginalized populations, from getting health care. We support this provision of the rule and encourage HHS to issue guidance explaining in more detail how covered entities can improve the collection of data on sex and gender to address disparities and avoid discrimination against and harm to Non-Binary and Gender Diverse people.

Specifically, with regard to Transgender individuals, discrimination persists. This also includes discrimination based on religious or moral grounds and with regards to Proposed § 92.206(b)(2) and (b)(4). Examples of this discrimination, which provide support for the provisions in the Proposed Rule, include the following:

- In 2015, a mother took her fourteen-year-old transgender son to a Children's Hospital in San Diego, a covered entity under § 1557. She sought treatment for his suicidal ideation associated with gender dysphoria. Even though hospital staff knew that the patient was a "transgender boy in acute psychological distress," nurses and other hospital staff "repeatedly addressed and referred to him as a girl, using feminine pronouns . . . which caused him extreme distress." The hospital discharged him before his medical hold expired instead of treating him. Five days later, he died by suicide. His mother later explained that her son "got worse because staff continued to traumatize him by repeatedly treating him as a girl and ignoring his serious health issues."[144]

- Numerous medical providers in Mississippi told a transgender woman they would not treat her for the flu.[145]

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[144] Brief of Nonprofit Civil Rights, Advocacy and Public Interest Organizations as Amicus Curiae at 22-23, *Kadel v. North Carolina State Health Plan*, No. 20-1409 (4th Cir. Oct. 7, 2020) (available from NHeLP).

[145] Br. of GLBTQ Legal Advocates & Defenders and 27 Other LGBTQ Advocacy Groups as Amici Curiae at 19-20, *Fulton v. City of Philadelphia*, No. 19-123 (Aug. 20, 2020), https://www.supremecourt.gov/DocketPDF/19/19-123/150770/20200820135738835_GLAD%20Amicus%20Br.%20-%20Fulton%20v%20%20Philadelphia%20-%20MASTER%20-TO%20FILE.PDF.

- A transgender man did not learn he had an aggressive cancer until weeks after having a routine breast cancer exam. After finally receiving his diagnosis, the patient spoke to the treating physician who told this patient that he had been uncomfortable because he was transgender and that his first impulse was to recommend psychiatry rather than cancer treatment.[146]

- A transgender patient waited seven hours to be admitted at the emergency room after speaking with a staff member regarding his gender. Hospital staff acknowledged that the wait time was unusual; he had severe pain and a high temperature. A doctor later told his mother that he "would have been septic within 12 to 24 hours when [she] brought him in and he could have died."[147]

- A transgender woman at a hospital in California suffered mistreatment that appeared to be linked to her transgender status. A doctor asked her to strip in a hallway, refused to answer her questions, and later, would only inform her of the results of her X-ray from outside her room. She was also harassed by others at the hospital including the police officers to whom she tried to report the beating that had caused the injuries for which she was seeking care.[148]

- A transgender individual was denied a hormone prescription by a pharmacist because he did not approve of the purpose of the prescription. The individual, who lacked transportation, had to travel over ten extra miles to another pharmacy and was humiliated by the experience.[149]

- One doctor responded to a transgender woman who disclosed her gender identity by telling her, "I believe the transgender lifestyle is wrong and sinful."

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[146] *Id.*

[147] Br. for the Transgender Law Center et al. as Amici Curiae at 23, *Masterpiece Cakeshop v. Colorado Civil Rights Commission*, No. 16-111 (Oct. 30, 2017), https://www.scotusblog.com/wp-content/uploads/2017/11/16-111bsac-transgender-law-center.pdf.

[148] *Id.* at 24-25.

[149] Br. of Amicus Curiae Transgender Legal Defense and Education Fund at 11, *Masterpiece Cakeshop v. Colorado Civil Rights Commission*, No. 16-111 (Oct. 30, 2017), https://www.scotusblog.com/wp-content/uploads/2017/11/16-111_bsac_transgender_legal_defense_and_education_fund.pdf.

While waiting for the doctor to write her prescription, she felt compelled to answer uncomfortable questions about trans women and sexual intimacy.[150]

- A transgender woman in Dallas who sought mental health care because she had become suicidal was asked invasive and inappropriate questions about her genitals and transgender status by nurses and orderlies. Facility staff denied her use of her electric shaver, causing her to grow a beard. The staff loudly discussed her gender identity leading to all of the patients quickly knowing of her transgender status and two male patients sexually harassing her. She attempted suicide twice while at the facility due to this poor treatment.[151]

- A transgender patient was denied a medically necessary hysterectomy because the local hospital, where the physician who would perform the surgery had admitting privileges, forbid all care related to gender dysphoria on religious grounds.[152]

iv. Prohibited discrimination based on sex characteristics, including intersex traits

We commend HHS for also explicitly naming that sex discrimination encompasses discrimination on the basis of sex characteristics, including intersex traits, at Proposed § 92.101(a)(2). We agree with HHS that sex characteristics include genitals, gonads, chromosomes, hormonal factors, or other physical sex characteristics.[153] These protections are especially important to ensure access to care for Intersex people who have sex characteristics that do not fit dominant, binary definitions of male or female bodies. The rule also protects Transgender, Non-Binary, and Gender Diverse people from discrimination based on variations in and/or perceived sex characteristics that do not fit, nor assimilate into, dominant, binary definitions of male or female bodies. This protection will ensure, for example, that a clinician may not refuse to prescribe a necessary hormone blocker to a child who has intersex traits, but prescribe hormone

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[150] *Id.*

[151] *Id.* at 13.

[152] *Id.* at 13-14.

[153] *See* United Nations Human Rights: Office of the High Commissioner, *Fact Sheet: Intersex* (2017), https://www.unfe.org/wp-content/uploads/2017/05/UNFE-Intersex.pdf (accessed Aug. 30, 2022).

blockers to a child without intersex traits.[154] It would also prevent a doctor from refusing to provide a prostate exam to a Transgender woman because she has breasts and a vulva.[155]

v. Prohibited discrimination based on sex stereotypes

We strongly support HHS's inclusion of protections against discrimination based on sex stereotypes at § 92.101(a)(1), providing an explicit means of protection against discrimination that is deeply endemic to our health care system.[156] Sex stereotypes are stereotypical ideas about masculinity or femininity, such as expectations about how people should represent or communicate their gender to others.[157] They also include gendered expectations about roles based on sex. Sex stereotypes can reflect the belief "that gender can only be binary and thus that individuals cannot have a gender identity other than male or female."[158]

Longstanding Supreme Court precedent has established that sex discrimination includes discrimination related to sex stereotypes.[159] We support this protection because it is important to protect a variety of people from discrimination in health care. This provision ensures that all people—heterosexual and LGBQI+ people, as well as cisgender women and men, and Intersex, Transgender, Non-Binary, and Gender Diverse people—are protected from pervasive discrimination on the basis of gender stereotypes.

Stereotypes hinging on the supposed dichotomy of biological sex, like those of the supposed dichotomy of gender, have led to pervasive discrimination against Intersex

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[154] *See* Katherine Dalke, Hum. Rights Watch, *A Changing Paradigm: US Medical Provider Discomfort with Intersex Care Practices* at 1 (2017), https://www.hrw.org/sites/default/files/report_pdf/us_intersex_1017_web.pdf.

[155] *See, e.g.,* Joshua Sterling & Maurice M. Garcia, *Cancer Screening in the Transgender Population,* 9 TRANS. ADROL. UROL. 2771, 2772 (2020).

[156] Proposed § 92.101(a)(2).

[157] Mara Youdelman et al., Nat'l Health L. Prog.*, Questions and Answers on the Proposed Rule Addressing Nondiscrimination Protections Under the ACA's Section 1557* (2022), https://healthlaw.org/resource/qa-proposed-rollback-of-nondiscrimination-protections-under-the-acas-section-1557.

[158] 81 Fed. Reg. 31392.

[159] *See, e.g.*, *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

people for decades. This dichotomy is a product of colonialism and Christian doctrines, which violently erased the histories and lived experiences of civilizations that recognized gender non-conformity and gender-expansiveness in their societies. The violent indoctrination demanded strict adherence to the status quo established through binary gender roles.[160] For example, health care providers may exclude Intersex people from receiving treatment that is typically coded as "male" or "female," such as pap smears or testicular cancer screening.[161] Intersex children face discrimination when they are exposed to risky and medically unnecessary surgical procedures that would not be deemed acceptable for non-intersex children.[162] Thus, the Proposed Rule's protections against sex discrimination that explicitly recognize the kinds of discrimination experienced by Intersex people are urgently needed

This protection is also vital to addressing inequities and eliminating barriers for members of the LGBTQI+ community, who often confound stereotypes when they do not conform to sex and gender norms. In addition, this protection is important to address health disparities among Intersex people, whose bodies often exist in ways that counter sex stereotypes, and who are subjected to coercion and discrimination in the health system. It will ensure that a hospital does not delay in providing a Transgender man a pregnancy test, based on a stereotype that men do not get pregnant.[163] The protection will shield an Intersex man from being told that his intersex traits are a problem to be fixed, based on stereotypes about what physical sex characteristics a man should have.[164]

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[160] Genny Beemyn, *Transgender History in the United States* (2d. Ed. 2022), https://www.umass.edu/stonewall/sites/default/files/Infoforandabout/transpeople/genny_beemyn_transgender_history_in_the_united_states.pdf.

[161] *See, e.g.,* Nat'l LGBTQIA+ Health Ed. Ctr., *Affirming Primary Care for Intersex People* 6 (2020), https://www.lgbtqiahealtheducation.org/wp-content/uploads/2020/08/Affirming-Primary-Care-for-Intersex-People-2020.pdf; Stephanie Dutchen, *The Body, The Self*, Harvard Med., Spring 2022, https://hms.harvard.edu/magazine/lgbtq-health/body-self.

[162] Cathren Cohen, Nat'l Health L. Prog., *Surgeries on Intersex Infants are Bad Medicine* (2021), https://healthlaw.org/surgeries-on-intersex-infants-are-bad-medicine/.

[163] *See, e.g.,* Marilynn Marchione, *Nurse Mistakes Pregnant Transgender Man as Obese. Then, the Man Births a Stillborn Baby*, USA TODAY, May 16, 2019, https://www.usatoday.com/story/news/health/2019/05/16/pregnant-transgender-man-births-stillborn-baby-hospital-missed-labor-signs/3692201002.

[164] *See, e.g.,* Katherine Dalke, Hum. Rights Watch, *A Changing Paradigm: US Medical Provider Discomfort with Intersex Care Practices* 1 (2017), https://www.hrw.org/sites/default/files/report_pdf/us_intersex_1017_web.pdf.

Explicitly naming sex stereotypes in the definition of sex discrimination will also protect women from pervasive discrimination in health care service delivery and coverage. This problem is ancient. For thousands of years, sex stereotypes have driven health care providers to discriminatorily misdiagnose women with "hysteria," an umbrella explanation crafted for a wide range of physical and behavioral symptoms that only affected people with uteruses.[165] The American Psychiatric Association recognized hysteria as an official diagnosis until the 1980 Diagnostic and Statistical Manual of Mental Disorders.[166] In more recent decades, health care providers have rebranded symptoms experienced by people with uteruses as "medically unexplained symptoms" and other umbrella terms.[167]

Today, women and people assigned female at birth, and especially people of color, continue to experience persistent sex stereotypes in health care delivery, as well as interconnected racism and ableism that compound this discrimination. Health care providers often label women and people with uteruses, and especially Black and other women of color "chronic complainers" and tell them that their symptoms are "all in their head."[168] As a result, women and people with uteruses, and especially people of color, often experience years- or decades-long delays in accurate diagnosis and treatment for serious conditions. For example, average estimates of diagnostic delay for people with endometriosis range from 7–11 years.[169] Sex stereotypes also often underpin the mistreatment of women and people with uteruses in reproductive and sexual health care and beyond. Providers are also much more likely to prescribe women with sedatives,

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[165] *See, e.g.*, *The History of Hysteria*, McGill Univ. Off. Sci. & Soc'y, https://www.mcgill.ca/oss/article/history-quackery/history-hysteria (last visited Aug. 9, 2022).
[166] *Id*.
[167] *See, e.g.*, Anushay Hossain, *The Pain Gap: How Sexism and Racism in Healthcare Kill Women* 47 (2021).
[168] *Id.* at 46; Vidya Rao, *'You Are Not Listening to Me'*, Today (Jul. 27, 2020, 9:44 AM), https://www.today.com/health/implicit-bias-medicine-how-it-hurts-black-women-t187866; Women in Pain Survey, *National Pain Report* (2014), https://www.surveymonkey.com/results/SM-P5J5P29L/.
[169] Omar T. Sims, *Stigma and Endometriosis: A Brief Overview and Recommendations to Improve Psychosocial Well-Being and Diagnostic Delay*, 18 Int. J. Environ. Res. Pub. Health 8210 (2021).

rather than pain medication, for their symptoms than men.[170] This discriminatory practice likely disproportionately impacts and harms Black women, who are subjected to both sexism and racism in health care, because providers are half as likely to prescribe Black patients with pain medication than white patients.[171] As we discuss below, discrimination is also pervasive in U.S. maternity care (see § 92.101(a)(1)(iii) of our comments).

Restoring implementation of § 1557's protections against sex stereotypes will ensure that a woman who seeks assistance with pain management is not dismissed as "emotional" or "hysterical," because of sex stereotypes that women are "overly sensitive."[172] It will also offer recourse to people subjected to related harms. We believe that it will also help deter heath care discrimination based on sex stereotypes and incentivize preventive measures, such as training to recognize and address implicit gender bias in health care.

vi. Prohibited sex discrimination related to pregnancy or related conditions, including termination of pregnancy

Discrimination related to pregnancy or related conditions continues to be widespread. This includes practices and policies in health care delivery, health insurance, and health-related coverage that obstruct access to abortions, maternity care, contraception, assisted reproduction (including fertility care, and other reproductive health services); discrimination based on past utilization of these services or reproductive health decisions; and discrimination in health care delivery for pregnancy or related conditions (see our comments on Proposed §§ 92.206 and 92.207 below).

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[170] Laura Kiesel, *Women and Pain: Disparities in Experience and Treatment*, HARVARD HEALTH BLOG (Oct. 2017), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562.

[171] *See, e.g.,* Astha Signhal et al., *Racial-Ethnic Disparities in Opioid Prescriptions at Emergency Department Visits for Conditions Commonly Associated with Prescription Drug Abuse*, PLOS ONE (Aug. 8 2016), https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0159224.

[172] *See, e.g., What to Know about Gender Bias in Healthcare*, MED. NEWS TODAY, Oct. 21, 2021, https://www.medicalnewstoday.com/articles/gender-bias-in-healthcare.

Discrimination related to abortion, an important health care service, is particularly pervasive.[173] Due to longstanding restrictions on abortion access, including the Hyde Amendment, many people were not able to access abortion care even prior to the Supreme Court's recent ruling in *Dobbs v. Jackson Women's Health Organization*.[174] However, *Dobbs*' increasing harms to § 1557 implementation cannot be overstated. The subsequent sweeping state-by-state loss of abortion rights has opened the floodgates for discrimination related to pregnancy and related conditions. Abortion providers, pharmacies, and covered entities writ large are grappling with how to comply with *Dobbs*. For example, as HHS has recognized, the Emergency Medical Treatment and Labor Act (EMTALA) requires that hospital emergency departments provide patients with emergency medical conditions with stabilizing treatment, or, if necessary, an appropriate transfer to another hospital with the capacity to provide care, yet covered entities are disregarding these protections.[175] States are considering banning out-of-state-travel for abortion.

Within thirty days of the *Dobbs* decision, eleven states had banned abortion, with some imposing criminal penalties.[176] This number continues to grow: twenty six states are likely to ban or have already banned abortion, leaving people without access to care in their state. As more and more states ban abortion under *Dobbs* and people must travel further and further in order to access care, financial and logistical barriers are increasingly insurmountable, particularly for Black, Indigenous and People of Color (BIPOC), people with low incomes, immigrants, young people, people with disabilities, LGBTQI+ people, and people with LEP, who have always been disproportionately subjected to and harmed by abortion barriers.[177] Communities also face an increased threat of arrest and prosecution as states seek to criminalize abortions and other

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[173] Madeline T. Morcelle, Nat'l Health L. Prog., *Fostering Equitable Access to Abortion Coverage: Reversing the Hyde Amendment* 4 (2021), https://healthlaw.org/resource/fostering-equitable-access-to-abortion-coverage-reversing-the-hyde-amendment.

[174] *Id*.; *Dobbs v. Jackson Women's Health Organization*, 597 U.S. __ (2022).

[175] *See, e.g.*, Letter from Xavier Becerra, HHS Secretary, to health care providers (Jul. 11, 2022), https://www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf.

[176] Marielle Kirstein et al., *One Month Post-Roe: At Least 43 Abortion Clinics Across 11 States Have Stopped Offering Abortion Care*, GUTTMACHER (July 28, 2022), https://www.guttmacher.org/article/2022/07/one-month-post-roe-least-43-abortion-clinics-across-11-states-have-stopped-offering.

[177] *See* Morcelle, *supra* note 173, at 4.

reproductive and sexual health care.[178] Out-of-pocket costs for abortions are often prohibitively high for people living near the federal poverty level (FPL).[179] Beyond the cost of care itself, access often requires costly travel, childcare, overnight stays, and forgone wages.[180] The Hyde Amendment, which bans federal funding for abortion coverage or care, forces many people with low incomes to endure financial hardships and forgo rent, groceries, utilities, or other necessities for their families as they scrape together money for their abortions and related expenses.[181] Many cannot come up with the necessary funds before hitting states' gestational limits on abortion access.[182] Thus, Hyde has forced one in four women in Medicaid who seek abortions to carry their pregnancies to term, and undoubtedly many Transgender, Non-Binary, Gender Non-Conforming, Gender Expansive, and other Gender Diverse people as well.[183]

The abortion crisis is also exacerbating our severe maternal morbidity and mortality epidemic. Because of structural racism, Black and Indigenous women and birthing

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[178] *See, e.g.*, *Tracking the States Where Abortion is Now Banned*, N.Y. TIMES (Aug. 9 2022), https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html. For example, the consequences of the Dobbs decision will fall especially heavy on transgender men, who must navigate compounded stigma when seeking abortion care. *See, e.g.,* Nic Lloyd & Kristin Canning, *Transgender And Non-Binary People Like Me Get Pregnant And Have Abortions Too*, WOMEN'S HEALTH (Jul. 8, 2021), https://www.womenshealthmag.com/health/a36807604/transgender-non-binary-abortion.

[179] *See, e.g.,* Sarah C.M. Roberts et al., *Out of Pocket Costs and Insurance Coverage for Abortion in the United States*, 24 WOMEN'S HEALTH ISSUES 211 (2014).

[180] *See, e.g.,* Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States* 49 PERSPECTIVE ON SEXUAL & REPRO. HEALTH 95 (2017); Rachel K. Jones et al., Guttmacher Inst., *New Evidence: Texas Residents Have Obtained Abortions in at Least 12 States That Do Not Boarder Texas* (2021), https://www.guttmacher.org/article/2021/11/new-evidence-texas-residents-have-obtained-abortions-least-12-states-do-not-border (finding that amid implementation of S.B. 8, a six-week abortion ban, many Texans are "finding out-of-state care to be cost prohibitive or too logistically challenging").

[181] *See, e.g.*, Amanda Dennis et al., *Does Medicaid Coverage Matter? A Qualitative Multi-State Study of Abortion Affordability for Low-Income Women*, 25(4) J. OF HEALTH CARE FOR THE POOR & UNDERSERVED 1571 (2014).

[182] *See* Stanley K. Henshaw et al., Guttmacher Inst., *Restrictions on Medicaid Funding for Abortion, A Literature Review* (2009), https://www.guttmacher.org/report/restrictions-medicaid-funding-abortions-literature-review.

[183] *Id*.

people face considerably higher risks of severe and life-threatening health complications from pregnancy.[184] Many states with the most extreme restrictions on abortion access are also those facing the worst maternal health crises, especially for Black women and birthing people.[185] We address additional ways in which *Dobbs* is impeding § 1557 protections in our later comments on Proposed §§ 92.206 and 92.207.

Accordingly, we strongly support HHS's inclusion of "pregnancy or related conditions" in its definition of sex discrimination in § 92.101 and urge HHS to strengthen this language. In the preamble to the Proposed Rule, HHS notes that although it does not propose restoring the 2016 language that the 2020 Final Rule eliminated, the same protections apply because § 1557 incorporates Title IX and its implementing regulations.[186] We agree that the "grounds" prohibited under Title IX apply and generally prefer HHS's proposal to include "pregnancy or related conditions" in Proposed § 92.101(a)(2). Proposed § 92.101(a)(2) offers a clearer and more concise definition of discrimination on the basis of sex. However, given the pervasive- and fast-growing nature of abortion-related sex discrimination, we urge HHS to specifically include termination of pregnancy in its regulatory text following "or related conditions." As we discuss in our comments below, we also urge HHS to enumerate specific forms of prohibited discrimination related to pregnancy or related conditions, including abortions and beyond, in §§ 92.206 and 92.207.

In addition, HHS does not define pregnancy-related sex discrimination consistently in the Proposed Rule. Proposed § 92.101(a)(2) notes that sex discrimination includes "pregnancy or related conditions" (emphasis added), yet Proposed §§ 92.8 and 92.10 include only "pregnancy," and exclude "or related conditions," in the parentheticals that follow sex discrimination. For the sake of clarity, we urge HHS to use consistent language regarding "pregnancy or related conditions, including termination of pregnancy" throughout the final rule.

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[184] *See, e.g.,* Lauren J. Ralph et al., *Self-reported Physical Health of Women Who Did and Did Not Terminate Pregnancy After Seeking Abortion Services*, 171 ANNALS INTERN. MED. 238 (2019); Caitlin Gerdts et al., *Side Effects, Physical Health Consequences, and Mortality Associated with Abortion and Birth after an Unwanted Pregnancy*, 26 WOMEN'S HEALTH ISSUES 55 (2016).

[185] Black Maternal Health Federal Policy Collective (BMHFPC), *The Intersection of Abortion Access and Black Maternal Health* (2022), https://tcf.org/content/facts/the-intersection-of-abortion-access-and-black-maternal-health.

[186] 87 Fed. Reg. 47878.

vii. Prohibited intersectional discrimination

One of § 1557's most groundbreaking innovations in U.S. health policy was its creation of protections against intersectional discrimination. We are encouraged to see the Department recognize in the preamble to the 2022 Proposed Rule that people may experience discrimination in health care on more than one basis.[187] As we discuss throughout our comments, intersectional discrimination is pervasive in health care. As noted above in § 92.101(a)(1)(ii) of our comments, Black women who are pregnant or seeking care for chronic pain are frequently subjected to health care discrimination that cannot be parsed out into separate forms of sex, race, and/or disability discrimination. People with disabilities often experience multiple barriers to sexual and reproductive health care.[188] For example, among subspecialty provider offices, forty four percent of gynecology offices were inaccessible due to factors such as inaccessible equipment and lack of transfer assistance, leaving wheelchair users unable to access abortion or maternal care.[189] In addition, a recent study found that Transmasculine people of color reported experiencing profound discrimination in health care at both a structural and interpersonal level.[190]

Thus, while we appreciate HHS's discussion of intersectional discrimination in the preamble, HHS must clarify § 1557's intersectional protections throughout the regulatory text. HHS should strengthen the text of Proposed § 92.101(a)(1) to this effect. We offer additional recommendations on how HHS must strengthen implementing regulations related to intersectional protections in our comments on enforcement mechanisms.

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[187] See, *e.g.*, 87 Fed. Reg. 47847.

[188] Nicole Agaronnik, *Ensuring the Reproductive Rights of Women with Intellectual Disability*, J. INTELLECT. DEV. DISAB. (manuscript) (Jun. 10, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8765596.

[189] Tara Lagu & Nicholas Hannon, *Access to Subspecialty Care for Patients With Mobility Impairment*, ANNALS OF INTERNAL MED. (Mar. 19, 2013), https://www.acpjournals.org/doi/10.7326/0003-4819-158-6-201303190-00003.

[190] *See* Madina Agénor et al., *Experiences of and Resistance to Multiple Discrimination in Health Care Settings Among Transmasculine People of Color*, 22 BMC HEALTH SERVS. RES. 369 (2022); *see also* Nat'l Black Justice Coalition et al., *Injustice at Every Turn* 3 (2009), https://www.thetaskforce.org/wp-content/uploads/2019/04/Injustice-at-Every-Turn-2009.pdf (Black Transgender people were more likely to experience discrimination in health care than either their white Transgender or Black cisgender counterparts).

RECOMMENDATION: Amend § 92.101(a)(1) as follows:

(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, ***or any combination thereof,*** 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***, including termination of pregnancy***; sexual orientation; and gender identity.

C. Proposed § 92.101(b)(1))

Proposed § 92.101(b)(1) applies regulations implementing § 504 of the Rehabilitation Act to health programs or activities that receive federal financial assistance, State Exchanges, and Federally Facilitated Exchanges. Specifically, the proposed section incorporates by reference 45 C.F.R. Parts 84 and 85, regulations pertaining to program accessibility.

We support HHS's general goal of explicitly incorporating into paragraph (b) the specific prohibitions on discrimination found in each of the civil rights laws on which § 1557 is grounded. We think this approach is prudent, given that some health care entities may not be readily familiar with the specific regulatory standards and obligations that apply to them under § 504 and the ADA.

However, care must be taken not to incorporate standards that do not fully reflect the requirements of § 1557 or the changes the ACA brought to nondiscrimination in health care. We are specifically concerned that the incorporation of 45 C.F.R. §§ 84.22 and 85.42, § 504's regulations pertaining to the accessibility of existing facilities, will create inconsistencies regarding the obligations of covered entities. Additionally, we object to the incorporation of § 84.23(c), which applies an outdated standard (the Uniform Federal Accessibility Standards) to new constructions.

i. 45 C.F.R. §§ 84.22 and 85.42

First, we are concerned with the incorporation by reference of §§ 84.22 and 85.42 to health care entities covered under § 1557. These regulations incorporate a concept of "program accessibility" that was developed in the 1990s for existing government facilities. The concept allowed government programs to assess the physical accessibility of a program or activity "in its entirety,"[191] in recognition that many federal and federally funded operations took place in older buildings and locations that would be difficult to modify in every instance. The regulations also stated that the standard "does not require a recipient to make each of its existing facilities or every part of a facility" accessible to and useable by people with disabilities.[192]

While this concept of "overall accessibility" may have been appropriate to apply to federal and federally funded programs forty years ago, it is not appropriate to apply to the broad array of health programs and activities covered by § 1557. In particular, we are concerned about the application of this standard to health insurers. The application of the "in its entirety" standard to these programs could theoretically allow an insurer to claim that their network is "accessible," even if there is discrimination in individual provider settings.

To be clear, health providers are already independently subject to the accessibility requirements of Title III of the ADA and/or § 504, as well as additional provisions of § 1557 (including proposed § 92.203, related to accessible buildings and facilities). Additionally, the general prohibition on discrimination at proposed § 92.101(a) should take primacy over the specific forms of discrimination at paragraph (b)(1). However, the incorporation of §§ 84.22 and 85.42 creates inconsistency, seeming to allow discrimination within larger "programs," even when their subparts are independently subject to nondiscrimination requirements.

To address this inconsistency, we recommend that HHS review the incorporation of §§ 84.22 and 85.42 and, if necessary, clarify that the "subparts" of programs must also comply with § 1557's nondiscrimination prohibitions.

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[191] 45 C.F.R. §§ 84.22(a), 85.42(a).
[192] *Id.* §§ 84.22(a), 85.42(a)(1).

ii. 45 C.F.R. § 84.23(c)

Second, we object to the wholesale incorporation of Part 84 because it would incorporate § 84.23(c), a provision that allows facilities to only conform with the Uniform Federal Accessibility Standards ("UFAS"), instead of the more recent 1991 Americans with Disabilities Act Standards for Accessible Design ("1991 Standards") or 2010 ADA Standards for Accessible Design ("2010 Standards").

UFAS is outdated and functionally deficient for people with disabilities, as HHS itself recognized when it explicitly declined to incorporate § 84.23(c) into the original § 1557 regulations.[193] In particular, UFAS permits facilities to maintain barriers that exclude people with disabilities that impact their mobility or strength. For example, it allows hazardous ramp slopes, permits inaccessible showers, and gives little consideration to the unique accessibility needs in medical care facilities. It is inappropriate to incorporate this nearly 40-year-old standard into the § 1557 regulations.

Additionally, incorporating § 84.23(c) creates an inconsistency within the § 1557 regulations. Proposed § 92.203(b)–(c) retains a thoughtful standard for the architectural accessibility of covered facilities, requiring constructions and alterations on or after July 18, 2016 to comply with the 2010 Standards and those before that date to comply with the 1991 Standards (with more lenient standards for newly-covered entities). The incorporation of § 84.23(c)—while certainly not absolving a covered entity of its obligation to comply with proposed § 92.203—creates confusion. We recommend omitting this provision from the incorporated regulations at proposed § 92.101(b)(1)(i).

RECOMMENDATION: Add the following language to § 92.101(b)(1)(i):

> (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 ***(except for § 84.23(c))***, 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

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[193] "We do not propose adopting the program accessibility provision at § 84.23(c), addressing conformance with the Uniform Federal Accessibility Standards for the construction and alteration of facilities, because these standards are outdated." 80 Fed. Reg. 54181.

provisions that use the term “student,” “employee,” or “applicant,” these terms shall be replaced with “individual.”

SUBPART C – SPECIFIC APPLICATIONS TO HEALTH PROGRAMS AND ACTIVITIES

§ 92.201 Meaningful access for limited English proficient individuals

We appreciate the Proposed Rule’s recognition that language services must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency, consistent with long-standing HHS LEP Guidance.[194] In evaluating what is “timely” the covered entity should provide language assistance at a place and time that ensures equal access to persons of all national origins and avoids the delay or denial of the “right, service, or benefit at issue.” Timely services mean that consumers and patients should not wait for more than thirty minutes to receive interpreter services, since at a minimum, a telephone interpreter should be available until an in-person interpreter can be located.

A. Timeliness

We commend HHS for including a timeliness factor in the regulation. However, we recommend including a specific time limit for written translations, such as: covered entities must translate all newly developed vital documents into threshold languages within 30 days after the English version is finalized. Otherwise, it is left to the entity to determine timely and some documents may not be available.

We support the provisions related to meaningful access including the requirements related to machine translation. Regarding the section on “evaluation of compliance”, we raise similar concerns to the ones above related to the lack of a requirement to develop a language access plan. We appreciate that OCR will evaluate the entity’s written language access procedures but those procedures will only be as good as the information on which they are based. The Proposed Rule does not seem to require covered entity to gather information about the needs of LEP individuals in its service area prior to developing policies and procedures.

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[194] HHS LEP Guidance, *supra* note 89.

We also support the clarification in the 2022 Proposed Rule related to the restricted use of certain persons to interpret or facilitate communication. The prior regulations recognized that an LEP individual cannot be required to provide their own interpreter. And that a minor can only be used to interpret in an emergency and that an adult accompanying an adult should not act as an interpreter without the person's consent or in an emergency. The 2022 Proposed Rule adds an expectation that in an emergency situation, the reliance an accompanying adult or minor should be "a temporary measure". We support this addition.

B. Using Accompanying Adult as an Interpreter

We appreciate the recognition that an adult accompanying an LEP individual generally should not be used as an interpreter. However, the 2022 Proposed Rule would allow a LEP individual to request an accompanying adult interpret or facilitate communication. We are concerned that in many situations that an LEP individual requests this, the LEP individual may not accurately understand their rights to a free, timely interpreter or that an accompanying adult could still be present and serve as a support for the LEP individual. Thus, we would suggest that HHS describe the steps that should occur before a covered entity accedes to an LEP individual's request. That is, if an individual wishes to use an adult accompanying her as her interpreter, a series of steps should occur:

1. The covered entity should again inform the individual that language services are available free of charge;
2. The covered entity should inform the individual the accompanying adult may accompany the individual even if the adult is not serving as an interpreter and that the accompanying adult may be better suited to serve as an advocate for the patient rather than interpreter;
3. If the individual still wishes to use the accompanying adult as an interpreter, the covered entity shall:
    a. Use a qualified interpreter to obtain a signed waiver of language services from the individual;
    b. Have a qualified interpreter monitor the interaction of the individual, accompanying adult and covered entity staff to assess if the accompanying adult is a qualified interpreter. If the accompanying adult is not able to provide qualified interpreting, the qualified interpreter steps in to ensure effective communication.

As the Proposed Rule recognizes, covered entities would be required to document that this information is provided. We would also suggest that if there is no documentation, it would be assumed the individual with limited English proficiency did not get the information and the covered entity would be not in compliance with § 1557. A prior report we issued on malpractice and language access noted:

> Physicians are taught that if an activity is not documented in the medical record, it did not happen. In reliance on this practice, if the medical chart did not show that a professional interpreter was used, this report concluded that none was used.[195]

We believe the same concept should apply with regards to covered entities documenting compliance with § 1557. Covered entities must be required to document the provision of language services and an individual's decision to use an accompanying adult or it should be presumed not to have happened.

We also suggest HHS specify that merely because an individual with LEP used an accompanying adult one time that this does not mean the covered entity can assume the individual with LEP will continue to bring that same adult or choose to use that adult as an interpreter. Rather, the covered entity must offer language services each and every time it encounters an individual with LEP.

We also urge HHS to incorporate a statement that as was stated in the preamble to the 2016 § 1557 NPRM, "a covered entity cannot coerce an individual to decline language assistance services."[196] As written, proposed subsection (e) does not capture this important concept and covered entities should be explicitly prohibited from discouraging individuals with LEP from exercising their rights, which is a form of discrimination unto itself.

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

[196] 80 Fed. Reg. 54184.

C. Remote Video Interpreting

We appreciate the restoration of requirements related to video interpreting. The 2020 Final Rule deleted requirements related to video interpreting for LEP individuals. Yet many covered entities may use video interpreting not only for deaf or hard-of-hearing patients but also LEP patients. The quality of video interpreting should be the same for all individuals who use it.

As mentioned above in the definitions section, we recommend that HHS add a requirement that a “companion” of an LEP individual who needs language services must also be provided meaningful access including access to qualified interpreters and translated materials. The 2022 Proposed Rule requires covered entities to take appropriate steps to ensure effective communication for companions of individuals with disabilities. We believe the same should be afforded to LEP individuals, particularly LEP parents/guardians of English-speaking minors/incapacitated adults and also family members, friends or associates of LEP individuals who are appropriate persons with whom a covered entity should communicate. This could include individuals who participate in decision-making with the LEP individual or need to understand the information for caregiving and other related reasons.

D. Oral Interpreting

We recommend that HHS require that oral interpreting services be provided in **all** cases where requested or needed although the manner of providing these services (in-person, telephonic, video) may differ depending on the entity and frequency of language. Consistent with HHS LEP Guidance, covered entities may provide oral interpreting services through the range of options that are available and evaluate the type and manner using a fact-dependent inquiry. This avoids an overly prescriptive approach, but provides clarity that some form of oral interpreting services must be provided in all cases where needed to constitute meaningful access. In doing so, this approach provides a reasonable balance and provides covered entities with needed flexibility by codifying existing standards that are already required for some entities.

For example, many smaller covered entities may find that contracting with a telephonic interpreter line, such as that required by the ACA Marketplaces and QHPs. They can provide meaningful access in some cases, while contracting with interpreters or employing staff interpreters may be necessary where communications are likely to affect the health and well-being of an individual and where the covered entity frequently interacts with LEP persons, such as in a hospital. We believe this requirement should be explicit in the regulation to ensure covered entities understand the minimum requirements to provide meaningful access.

§ 92.202 Effective communication for individuals with disabilities

Section 92.202(a) requires covered entities to take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with non-disabled individuals. Section 92.202(b) requires covered entities to provide appropriate auxiliary aids and services. Examples of problems individuals with disabilities have faced in receiving effective communication include the following:

- A hospice care provider refused to provide a deaf son who was the primary caretaker of his mother, the care recipient, with an interpreter. This prevented him from communicating about his mother's end-of-life care with the care team.[197]

- A hospital failed to provide a deaf person in need of emergency medical care with any accommodation. This left the deaf patient to resort to handwritten notes as the only means of communication, a much less effective way to communicate one's needs.[198]

- A deaf woman with a high-risk pregnancy asked for an interpreter during childbirth. Hospital staff dismissed her request, leading her to suffer embarrassment and humiliation as she gave birth.[199]

We recommend Proposed § 92.202(b) explicitly parallel the language in Proposed § 92.201(b) by stating that auxiliary aids and services must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making of the individual with a disability. While those requirements and others are incorporated through § 92.202(a)'s reference to 28 C.F.R. §§ 35.160-164, smaller covered entities that are creating 1557 policies and procedures without necessarily obtaining legal

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[197] Br. of Amici Curiae Disability Organizations at 13-14, *Cummings v. Premier Rehab Keller*, No. 20-219 (Aug. 30, 2021).

[198] *Id.* at 14.

[199] *Id.*

advice may simply look to §§ 92.201 and 92.202, noting the seeming difference in language between the subsections. OCR's provision of technical assistance that addresses specifically and in plain language what is required under 28 C.F.R. § 35.160-164, in conjunction with what is required under § 92.201 of the proposed rule, will also be helpful.

§ 92.203 Accessibility for Buildings and Facilities

A. General Standard

NHeLP supports HHS's proposal to add a general provision to § 92.203 (proposed paragraph (a)), echoing the language of the § 504 regulations and broadly 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.[200]

With this addition, we appreciate HHS's recognition that facility accessibility for people with disabilities goes beyond the architectural design and physical barriers that may be contained within a health care facility. Accessibility is needed by people with all sorts of disabilities, not just people with physical disabilities. It permeates every aspect of a facility—it is not just whether an individual can make it to and through the door, it is whether they can meaningfully access all health care services the facility or provider offers. Are there accessible tables, weight scales, and diagnostic equipment for people with mobility disabilities? Is the environment safe and accessible for individuals with sensory sensitivities? Are staff in the facility properly trained to accommodate and adapt to the needs of individuals with communication or mental health disabilities?

Proposed § 92.203(a) clarifies the protections that people with disabilities are guaranteed under § 1557, and it more closely aligns with the requirements of § 504 and the ADA. We agree that HHS should codify this provision.

Further, we recommend that HHS add a provision to § 92.203 making clear that compliance with the specific architectural design requirements at proposed § 92.203(b)–(c) does not, alone, satisfy the general requirement of proposed paragraph (a). This addition is particularly important in light of HHS's consideration of adding medical

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[200] 45 C.F.R §§ 84.4 & 85.21.

diagnostic equipment ("MDE") standards to the § 1557 regulations (discussed further *infra*). Facility accessibility is broader than architecture, and it is important to codify this concept. For consistency, the language could closely track the text at proposed §§ 92.101(b)(2) and 92.207(d).

RECOMMENDATION: Add the following language to § 92.203:

> ***(d)*** ***The enumeration of specific facility design standards in paragraphs (b) and (c) of this section does not limit the general applicability of the nondiscrimination prohibition in paragraph (a) of this section.***

B. Architectural Standards

NHeLP supports HHS's proposal to retain the existing provisions of § 92.203 (proposed paragraphs (b) and (c)), regarding the architectural standards for a covered entity's buildings and facilities. We agree that the 2010 Standards and, in limited circumstances, the 1991 Standards are the appropriate standards for facilities where health programs or activities are conducted.[201]

We emphasize the importance of a continued push towards universal compliance with the 2010 Standards. As the few health care entities who are not already subject to the 2010 Standards alter or update their facilities, it is critical that HHS provide oversight to ensure that such facilities come into compliance. Health care consumers with disabilities are promised greater accessibility under the 2010 Standards, as compared to the 1991 Standards. For example, the newer standards have specific provisions that apply to "medical care facilities," which require facilities to offer accessible patient rooms in every medical specialty unit.[202] Such contextual specificity makes the 2010 Standards more appropriate for adoption by § 1557 covered entities and more beneficial to individuals with disabilities.

The uniform application of the 2010 Standards will also enable greater consistency among implementing agencies, given the overlapping jurisdiction of HHS's Office for Civil Rights with the U.S. Department of Justice (the latter of which enforces the 2010 Standards as applied to ADA Title II entities). Complainants with disabilities should not have the added burden of trying to figure out the date on which a health care facility's

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[201] 28 C.F.R. pt. 36, § 35.104.
[202] 28 C.F.R. § 35.151(h).

construction or alteration began in order to then determine which administrative forum is appropriate to enforce their rights. We appreciate HHS's ongoing commitment to simplifying this process and ensuring that all health care facilities are physically accessible for people with disabilities.

C. Medical Diagnostic Equipment Standards

NHeLP recommends that HHS reference and incorporate the 2017 Standards for Accessible Medical Diagnostic Equipment ("MDE Standards"), 36 C.F.R. pt. 1195, into § 92.203. The MDE Standards, which implement § 510 of the Rehabilitation Act, set forth minimal technical criteria for the accessibility of MDE in facilities where health programs or activities are conducted.[203] Incorporating these standards into the § 1557 regulations is a necessary step towards improving access to health care services for individuals with disabilities.

As HHS has identified, people with disabilities continue to "fare worse on a broad range of health indicators than the general population."[204] For example, adults with disabilities are fifty-eight percent more likely to experience obesity, three times more likely to be diagnosed with diabetes, and nearly four times more likely to have early-onset cardiovascular disease.[205] They are also more likely to have high blood pressure and experience symptoms of psychological distress.[206]

These disparities in health outcomes are closely linked to a lack of timely access to quality primary and specialty health care services. Both children with disabilities and adults with disabilities are more than twice as likely as their nondisabled counterparts to

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[203] 29 U.S.C. § 794f; 36 C.F.R. pt. 1195.

[204] 87 Fed. Reg. 47836.

[205] Silvia Yee, et al., *Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity*, Nat'l Acads. Sci., Eng'g, & Med. (2017), *available at* https://dredf.org/wp-content/uploads/2018/01/Compounded-Disparities-Intersection-of-Disabilities-Race-and-Ethnicity.pdf; *see also, 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 (Apr. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5302214/; 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 (Apr. 2015), https://pubmed.ncbi.nlm.nih.gov/25263459/.

[206] Lisa Iezzoni et al., *Trends in U.S. Adult Chronic Disability Rates Over Time*, 7 DISABILITY & HEALTH J. 4, 402–12 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4167341/.

report unmet health care needs.[207] Further, adults with disabilities are significantly less likely to receive preventative and diagnostic health services, including primary care appointments, cervical cancer screenings, and mammograms.[208]

Disparities in access to care can be traced, in part, back to a widespread lack of accessible MDE in provider facilities. Examination tables, weight scales, and imaging equipment are critical to health maintenance and diagnosis, yet they are often not accessible for people with mobility disabilities.[209] For example, a recent study of nearly 4,000 primary care offices in California found that only nineteen percent of facilities had accessible examination tables, and only eleven percent of facilities had accessible scales.[210] Even when provider facilities have accessible MDE, staff is often not properly trained in how to use the equipment, leading to underutilization.[211]

The lack of access to accessible MDE compromises the quality of care that people with disabilities receive, and it can lead to missed or delayed diagnoses of potentially life-threatening conditions.[212] Further, the lack of accessible MDE in provider facilities has been shown to negatively impact the mental health of people with disabilities and cause many individuals to forgo needed preventative care.[213]

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[207] Yee et al., *supra* note 205, at 31.

[208] *See, e.g.*, *id.*; Brian S. Armour et al., *State-Level Differences in Breast and Cervical Cancer Screening by Disability Status: United States*, 19 WOMENS HEALTH ISSUES, no. 6, at 406-414 (Dec. 2009), https://pubmed.ncbi.nlm.nih.gov/19879454/; H. Stephen Kaye, *Disability-Related Disparities in Access to Health Care Before (2008–2010) and After (2015–2017) the Affordable Care Act*, 109 AM. J. PUB. HEALTH 7, 1015–21 (July 2019), https://pubmed.ncbi.nlm.nih.gov/31095413/; Michael Stillman et al., *Healthcare Utilization and Associated Barriers Experienced by Wheelchair Users: A Pilot Study*, 10 DISABILITY & HEALTH J. 4, 502–08 (Oct. 2017), https://pubmed.ncbi.nlm.nih.gov/28245968/.

[209] Nat'l Council on Disability, *Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities* 16 (May 20, 2021), https://ncd.gov/publications/2021/enforceable-accessible-medical-equipment-standards (hereinafter "NCD Report").

[210] Nancy Mudrick et al., *Presence of Accessible Equipment and Interior Elements in Primary Care Offices*, 3 HEALTH EQUITY 1, 275–79 (June 2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6585465/.

[211] NCD Report, *supra* note 209, at 16.

[212] *Id.* at 16–20.

[213] *See, e.g.*, Amanda Reichard et al., *Prevalence and Reasons for Delaying and Foregoing Necessary Care by the Presence and Type of Disability Among Working-Age Adults*, 10

In order to help alleviate the widespread lack of access to MDE, and the health disparities that result from it, HHS should issue regulations requiring § 1557 covered entities to comply with the MDE Standards at 36 C.F.R. pt. 1195. Although § 504, Titles II and III of the ADA, and § 1557 prohibit discrimination on the basis of disability in health care settings, systemic improvements in the accessibility of MDE have failed to materialize. Similar to the time period prior to the adoption of architectural design standards, covered entities have resorted to case-by-case solutions for MDE access and failed to incorporate appropriate systemic solutions.[214] Now, we have specific standards in hand. The U.S. Access Board developed comprehensive, vetted standards to combat widespread MDE access barriers.[215] While we recognize that HHS must still develop scoping requirements for these standards, and that this process will take time, we encourage HHS to take the first step towards greater accessibility by adopting the MDE Standards while the § 1557 regulations are otherwise being amended.

RECOMMENDATION: Add the following language to § 92.203:

> ***(d) Medical Diagnostic Equipment Standards.***
>
> ***(1) If a facility or part of a facility in which health programs or activities are conducted purchases or replaces medical diagnostic equipment on or after [30 DAYS FROM DATE OF PUBLICATION OF FINAL RULE], then such newly-acquired equipment shall comply with 36 C.F.R. part 1195.***
>
> ***(2) Each facility or part of a facility in which health programs or activities are conducted shall fully comply with 36 C.F.R. part 1195 by or before [24 MONTHS FROM DATE OF PUBLICATION OF FINAL RULE].***

Additionally, HHS requests comment on whether the lack of access to MDE would constitute a discriminatory benefit design or network inadequacy. We recommend that it HHS clarify that a lack of access to MDE can constitute both discriminatory benefit design and network inadequacy, depending on the facts of the situation.

DISABILITY & HEALTH J. 1, 39–47 (2017) https://pubmed.ncbi.nlm.nih.gov/27771217/; Carrie Basas, *Advocacy Fatigue: Self-Care, Protest, and Educational Equity,* 32 WINDSOR YEARBOOK OF ACCESS TO JUSTICE 2, 37 (2015), https://wyaj.uwindsor.ca/index.php/wyaj/article/view/4681.

[214] NCD Report, *supra* note 209, at 24–26.

[215] 29 U.S.C. § 794f; 36 C.F.R. pt. 1195.

Benefit design requirements, as articulated in proposed § 92.207(b)(2), require health insurers to proactively consider accessibility as an integral component of what constitutes a health care benefit.[216] For example, if a health plan covers primary care office visits, but providers do not have examination tables that are accessible to the patient (thus inhibiting or preventing a full examination), then meaningful access to that benefit has been denied. In other words, if access to a benefit depends on access to MDE, then lack of access to that MDE constitutes a discriminatory benefit design.

Likewise, if a health insurer or managed care entity fails to offer a provider network that consists of an adequate amount of primary care and specialty providers with accessible MDE, it could violate federal and state network adequacy requirements. Equipment accessibility should be considered in conjunction with other important components of network adequacy, such as time and distance standards and provider-member ratios.

Ultimately, lack of access to MDE relates to multiple aspects § 1557's nondiscrimination provisions. It is not only a straightforward violation of proposed § 92.203(a), concerning facility accessibility, but it also creates a ripple effect—impacting a covered entity's benefit design and network adequacy. To resolve this intractable problem, and assist covered entities in coming into compliance with § 1557, clear standards should be established. HHS should incorporate the above-suggested language in § 92.203.

§ 92.204 Accessibility of information and communication technology

A. <u>People with Disabilities</u>

i. Information and Communication Technology

We appreciate HHS's unequivocal recognition that health-related information and communication technology (ICT) must be accessible to and usable by people with disabilities to ensure effective and nondiscriminatory provision of health care services. We strongly support HHS's inclusion of explicit requirements in the Proposed Rule for accessible ICT. While Titles II and III of the ADA and §§ 504 and 508 of the

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[216] *See also, e.g.*, *Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 949 (9th Cir. 2020) (affirming that § 1557 prohibits discriminatory benefit designs); *Doe v. CVS Pharmacy, Inc.*, 982 F.3d 1204, 1211–12 (9th Cir. 2020) (affirming that a beneficiary must have "meaningful access" to a benefit).

Rehabilitation Act already provide strong legal protections for consumers and clear guidance for covered entities, the COVID-19 pandemic forced a rapid expansion of many of these communication technologies and often did so without consideration of the accessibility needs of people with disabilities. We support HHS's reaffirmation in this Proposed Rule of the general requirement to ensure accessible ICT, including websites and mobile applications, which should emphasize the need for dramatically greater compliance with current law.

We commend HHS for proposing to apply the nondiscrimination requirements to all of a covered entity's ICT and not to restrict the obligations only to websites or to specific classes or categories of ICT. All too often, covered entities apply a piecemeal approach to ensuring that consumers of health information with disabilities do in fact have full and equal benefit from their services, programs, and activities.[217] Far too frequently, access – if provided at all – is limited to a given context, such as accessible informed consent forms, with little appreciation of need to provide access at every stage of service delivery where all consumers are expected or invited to interact with online information or specific pieces of equipment. For example, a telehealth platform itself might be accessible but still create barriers if the technical instructions for setting it up are not accessible. Importantly, ICT must be able to be used by individuals with disabilities without requiring assistance unless that is the preferred accommodation by the individual with disabilities. Too often, we have heard of ICT that does not work independently for people with disabilities. First, accessibility standards require that ICT be independently navigable for a wide range of disabilities. Secondly, independence and privacy are very important in covered entities' programs and activities. Systems that require a person use assistance when they should not have to potentially deny care, inhibit access to the services, and diminish quality of care if a person cannot freely share their health issues or concerns.

Covered entities must understand that failing to provide access to consumers with disabilities at every stage of service delivery not only discriminates against people with disabilities, but puts individuals at tremendous risk. This includes appointment setting,

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[217] *See, e.g., Bone v. Univ. of N. Carolina Health Care Sys.,* No. 1:18CV994, 2022 WL 138644, at *15 (M.D.N.C. Jan. 14, 2022) (describing how a patient who is legally blind could use part of a covered entity's system independently, but needed assistance to read test results and needed paper versions of other documents to be able to access the covered entity's programs and services; also describing the struggles getting those accommodations with later decisions in this case describing what it would take to make the systems accessible).

in-person or online check-in, interaction with any and all devices with which a covered entity expects consumers to use both in the inpatient and outpatient contexts, review of medical records, billing and insurance data. The individual (or family member of a patient or program participant) with disabilities cannot fully understand diagnosis and treatment to make informed choices about health care providers, or appropriately respond to specific interventions, if the ICT they use is not accessible. That could threaten their needed services and benefits but even their health coverage itself. For example, they may not be able to identify billing and procedural coding errors timely if billing statements, summary notices, and summary of benefits documents are partially or fully inaccessible, even when provided in an electronic format.

We also anticipate that the proposal to cover all of a covered entity's ICT will assist healthcare professionals with disabilities to achieve greater independence and functional capacity as they exercise their profession. We know of numerous examples where people with disabilities in professions ranging from medical stenographer to licensed psychologists face additional ICT barriers after they have already undergone rigorous training, educational and testing regimens because a hospital or managed care organization's provider note and record systems are inaccessible to speech-reading software, for example.

There is no principled reason for any aspect of a covered entity's ICT systems to be designed or maintained in a manner that cannot interface with the range of functional human capacities affecting vision, hearing, and speed and range of motion; this holds true for ICT regardless of whether it is intended primarily or incidentally for public use. We also note that training, employing and retaining healthcare professionals with disabilities is a key means of reducing the widely recognized healthcare disparities experienced by people with disabilities.[218]

We strongly support the requirement that when determining whether an action would be an undue burden, a covered entity must consider all resources available for use in the funding or operation of the health program or activity. This is consistent with the

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[218] *See* Ctrs. for Medicare & Medicaid Servs., Office of Minority Health, *CMS Equity Plan for Improving Quality in Medicare* (Sept. 2015), http://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf; Gloria L. Krahn et al., *Persons with Disabilities as an Unrecognized Health Disparity Population*, 105 AMER. J. PUB. HEALTH. S198 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355692/pdf/AJPH.2014.302182.pdf.

interpretation of “undue burden” under § 504 and the ADA and helps prevent defenses that there is insufficient funding in the IT budget as a covered entity provides significant dividends to shareholders. We also appreciate an entity with an undue burden in making the technology accessible continues to have an obligation to provide information in an accessible format that would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits of that health program or activity.

We believe that it would be useful for HHS to publish guidance or FAQs that include examples of the various stages of health care delivery wherein online and ICT means employed by covered entities need to be accessible.

RECOMMENDATION: Amend § 92.204(a) by adding at the end:

> (a) …. ***When a covered entity uses information and communication technology, it must give primary consideration to the requests of individuals with disabilities and their preferred accommodations. In order to be effective, information and communication technology must be provided in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.***

ii. Accessibility Standards

We support the suggestion to require covered entities to comply with a specific set of accessibility standards. More specifically, we recommend creating a specific, clear, and enforceable requirement that covered entities’ ICT explicitly conform with the latest version of the Worldwide Web Consortium's Web Accessibility Initiative's Web Content Accessibility Guidelines, WCAG (WCAG Standards) at the AA level (“acceptable compliance”) within one year of update.[219]

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[219] Worldwide Web Consortium (W3C), Web Content Accessibility Guidelines (WCAG) 2.1 (June 5, 2018), https://www.w3.org/TR/WCAG21/#background-on-wcag-2 (hereinafter “WC3, WCAG”) For information on WCAG’s levels of compliance, *see* W3C, *Web Content Accessibility Guidelines (WCAG) 2 level AA Conformance,* https://www.w3.org/WAI/WCAG2AA-Conformance (last visited Sept. 27, 2022); *see also,* Accessible Metrics, https://www.accessiblemetrics.com/blog/what-are-the-levels-of-wcag-compliance/#:~:text=WCAG%202.0%20Level%20AA%3A%20Acceptable,people%20with%20or%20without%20disabilities (last visited Sept. 27, 2022).

This approach would have the benefit of clarity and consistency, and greater specificity will assist HHS in actual enforcement of the section. It will clearly inform HHS investigators that ICT that falls short of the § 504 or WCAG Standards falls within HHS's jurisdiction and their authority to require correction from covered entities. Although we note that because accessibility is determined at an individual level, HHS would still have authority to investigate claims of failures to accommodate individual needs. Covered entities will and must continue to engage interactively on how to make ICT fully accessible to individual consumers and employees. However, compliance with the latest WCAG standards will facilitate broad accessibility and create a good starting point in discussions about individual accommodations. The fact that DOJ is applying WCAG standards in its own Title II and III settlements supports our position that HHS should also adopt the WCAG Standards.

Standards like WCAG may be more frequently updated than regulations, and so may more likely to adapt to incorporate new technological innovations and reflect current best practices. We prefer WCAG to the Access Board standards because they are more explicit and comprehensive and are written to be testable and technology neutral, meaning they can more easily apply across technological formats.[220] HHS should require covered entities to maintain compliance with the most recent version of the standards at the AA level within a year of any update. HHS must also make abundantly clear, in regulations, that any published standards and updates remain publicly available at no cost.

In response to HHS's request for comment about using a set of published standards like WCAG as a safe haven for covered entities for the purposes of this section, we have concerns. While WCAG provides an excellent baseline for accessibility of web and mobile content, the standards may not encompass all forms of ICT included in HHS's proposed definition in 45 C.F.R. § 92.4, such as information kiosks, transaction machines, or telehealth interfaces, that are not centered on web or mobile content. As noted above, accessibility depends on making each step and component of the use of technology as accessible as possible. Creating a safe harbor based on content-focused WCAG standard might lead to oversight of important contextual details that are key to successful accessible communications.

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[220] U.S. Access Board, *Comparison Table of WCAG 2.0 to Original 508 Standards*, https://www.access-board.gov/ict/wcag2ict.html (last visited Sept. 19, 2022).

The § 508 regulations finalized in 2017 also create a safe harbor for legacy ICT that has not been modified or upgraded.[221] Given that many platforms for state Medicaid agencies date back thirty years or more, we are concerned that such exceptions may create perverse incentives preventing the modernization of Medicaid eligibility system to make them more accessible. We think the standard in § 1557 regulations should be higher.

Moreover, WCAG's standards note that:

> even content that conforms at the highest level (AAA) will not be accessible to individuals with all types, degrees, or combinations of disability, particularly in the cognitive language and learning areas.[222]

Because § 1557 protects accessibility at the individual level, covered entities still have an obligation under Proposed § 92.204 to seek and provide reasonable accommodations for individuals for whom ICT that meets published standards remains inaccessible. Creating a safe harbor requiring only that ICT meet a certain level of WCAG standards may make it harder for such individuals to obtain needed individual accommodations.

We do think it is important for HHS to reaffirm the rights of people with disabilities and provide means to redress current violations that occur when people with disabilities encounter ICT that fails to meet existing, readily available, and widely accepted standards. The approach of requiring covered entities to meet specific standards leaves room for the expected evolution of ICT requirements over time. We therefore support creating a clear, specific, and enforceable requirement that ICT meet the latest WCAG Standards at the AA level within one year of their release. Each ICT should include a conformance claim showing the type of conformance and evidence of the testing used to verify compliance.[223] This can only help to improve the full and equal participation of people with disabilities in America's health care marketplace. We think, however, that

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[221] Information and Communication (ICT) Standards and Guidelines, 82 Fed. Reg. 5790, 5803 (Jan. 18, 2017) (to be codified at 36 C.F.R. pts. 1193 & 1194).

[222] WC3, WCAG, *supra note* 219, at 0.2, https://www.w3.org/TR/WCAG21/#wcag-2-layers-of-guidance.

[223] WC3, *Understanding WCAG 2.0: Understanding Conformance*, https://www.w3.org/TR/UNDERSTANDING-WCAG20/conformance.html, (last visited Sept. 19, 2022).

creating a safe harbor for covered entities based on the published standards could be counterproductive for all individuals to receive ICT accommodations when needed.

B. Other Populations

We are concerned that proposed § 92.204 would focus on nondiscrimination and accessibility for individuals with disabilities only. Section 1557 is not limited to discrimination on the basis of disability alone; accordingly, § 92.204 should cover and prohibit discrimination on the basis of all enumerated grounds, including discrimination based on race, color, national origin, sex, and age, as well as disability. Including other protected classes would reinforce the importance of addressing accessibility for people who face intersectional discrimination, such as a person with a disability who is also LEP.

Section 1557 requires that individuals not be excluded from participation, denied benefits, nor suffer discrimination by any covered entity on all enumerated grounds, not just disability. Thus proposed § 92.204 regarding information and communication technology should be applicable not just to individuals with disabilities, but to all individuals covered by § 1557. The Office for Civil Rights should consider the benefits and barriers all protected classes might encounter in accessing electronic information technology in health programs and activities. If designed, built, and used correctly, health information technology can introduce important new solutions that reduce access and outcomes disparities across protected classes, including those with intersectional identities.

Accordingly, the HHS should not limit proposed § 92.204 to individuals with disabilities, but should broaden it so that it covers all other grounds protected by § 1557. This can be accomplished by amending the heading and inserting the broad provision:

RECOMMENDATION: Amend § 92.204 by amending the section title, inserting a new paragraph (a) prior to the propose paragraph (a), redesignating proposed paragraph (a) as paragraph (b), editing current paragraph (b) which would become (c) to include the WCAG standards, and redesignating subsequent paragraphs accordingly:

> ~~Accessibility of I~~ ***I***nformation and communication technology~~ for individuals with disabilities~~.
>
> ***(a)*** ***A covered entity must ensure that its health programs or activities provided through information and communication technology do not exclude individuals from participation in, deny them the benefits of, or subject them to discrimination under any health program or activity on the basis of race, color, national origin, sex, age or disability.***
>
> ~~(a)~~***(b)*** A covered entity must ensure that its health programs and activities provided through information and communication technology are accessible to individuals with disabilities, ...
>
> ~~(b)~~***(c)*** A recipient or State exchange . . . comply with the requirements of ***the most recent version of the Worldwide Web Consortium's Web Accessibility Initiative's Web Content Accessibility Guidelines, WCAG (WCAG Standards) at the AA level within one year of update***~~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

We support HHS's proposal to retain the previous standards that require covered entities to make reasonable modifications to policies, practices, or procedures. In particular, we appreciate that the term "reasonable modification" is consistent with regulations implementing Title II of the ADA at 28 C.F.R. § 35.130(b)(7). We also strongly recommend incorporating existing standards relating to accessible medical and diagnostic equipment that were developed by the U.S. Access Board and finalized in 2017 within the Proposed Rule.[224] For some people with disabilities, equipment accessibility is as necessary to equally effective healthcare as the accessibility of

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[224] Standards for Accessible Medical Diagnostic Equipment, 36 C.F.R. pt. 1195 (2017).

buildings and facilities, and is equally linked to requests for reasonable modifications in a covered entity's policies and procedures. See s*upra* discussion of § 92.203.

§ 92.206 Equal program access on the basis of sex

We strongly support HHS's restoration of a provision clarifying covered entities' obligations to provide equal access to health programs or activities free from discrimination on the basis of sex.[225] This section appropriately mirrors the 2016 Final Rule's conclusion that equal program access on the basis of sex extends to the provision of health services. Given § 1557's importance as the only federal civil rights law explicitly prohibiting sex discrimination in health care, it is important that the final rule include this specific application of the more general prohibition on sex discrimination under Proposed § 92.101.

HHS's proposed standards will help ensure that OCR can meaningfully investigate claims of sex discrimination. We support the *Arlington Heights* multi-factor test and the *McDonnell Douglas* burden-shifting framework among a non-exhaustive list of tools that OCR may utilize for investigating discrimination claims.[226] Together, these standards, established through longstanding civil rights case law, are appropriate to adjudicate sex-based § 1557 claims because such claims are challenging to prove despite the pervasiveness of sex discrimination. This approach accommodates the lived realities of LGBTQI+ people and women by allowing people to rely on different types of circumstantial evidence to collectively demonstrate a discriminatory act by a covered entity. The burden shifting framework also places the onus on the covered entity to provide a legitimate, nondiscriminatory reason for its actions.

HHS's enumeration of specific forms of prohibited sex discrimination in health programs and activities make this provision especially critical. These provisions provide much-

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[225] The 2016 Final Rule was the product of a lengthy and robust process of deliberation and public input; it was developed over the course of six years of study and following multiple comment periods, with over 25,000 comments from stakeholders, which were overwhelmingly supportive of inclusion of protections against discrimination based on pregnancy or related conditions, including termination of pregnancy, sex stereotyping, sexual orientation, gender identity, and more. HHS engaged stakeholders through listening sessions, participation in conferences, and other outreach prior to taking regulatory action.

[226] *Vill. of Arlington Heights v. Metro. Housing Dev. Corp*., 429 U.S. 252, 266–68 (1977); *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973).

needed clarity to some of the ways that sex discrimination manifests in health programs and activities. HHS's proposed language protects access to quality services free from sex discrimination for all individuals while recognizing the particular challenges that LGBTQI+ populations face. However, as we discuss in our comments on Proposed § 92.206(b) below, we urge HHS to enumerate forms of sex discrimination related to pregnancy or related conditions, including intersectional sex discrimination impeding access to treatments and medications for people with disabilities or emergency conditions. Given the pervasive and fast-growing nature of this discrimination, particularly following the Supreme Court's *Dobbs* decision, it is critical that HHS clarify these protections in the regulatory text and not leave them to guidance.

A. Proposed § 92.206(a)

We support the regulatory text of Proposed § 92.206(a). We believe that protection from discrimination on the basis of sex is critical to providing ethical, competent, comprehensive, and quality health services. LGBTQI+ people and women are particularly susceptible to encountering sex discrimination that impedes equal program access. For example, there are extensive gaps in education, awareness, and inclusion about the reproductive and sexual health needs of LGBTQI+ people in our health care system. This is likewise true for people with disabilities under § 1557. Black, Indigenous and People of Color (BIPOC) are subjected to sex discrimination related to sex stereotypes, pregnancy and related conditions, and other aspects in health services at disproportionate rates compared to white people.[227] These systemic gaps continue to stigmatize and widen ongoing health inequities without meaningful and enforceable ways to hold covered entities accountable. The proposed language in this provision is all the more urgent as hundreds of state-level legislative efforts seek to attack and erase the major, life-saving advancements in health care for Transgender, Non-Binary, and Gender Diverse people, people who are pregnant or have related conditions, and people with disabilities.

B. Proposed § 92.206(b)

We strongly support HHS's enumeration of specific forms of sex discrimination that undermine access to health programs and activities in Proposed § 92.206(b). However, the proposed regulatory text would repeat HHS's erroneous exclusion of forms of

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[227] *See* our comments on Proposed § 92.101(b) and the analysis that follows on Proposed § 92.206(b).

discrimination related to pregnancy from this section of the 2016 Final Rule.[228] Discrimination related to pregnancy or related conditions can manifest in many forms, and we acknowledge that it would be impossible to capture them all in Proposed § 92.206(b). We also understand per Proposed § 92.206(d) that this list of specific forms of discrimination is not exhaustive and does not limit the general applicability of Proposed § 92.206(a). With that said, it is vital that this subsection enumerate some of the most pervasive forms of discrimination related to pregnancy or related conditions, including termination of pregnancy, just as HHS proposes to do with discrimination related to sex assigned at birth, gender identity, gender otherwise recorded, gender-affirming care, and gender transition services.

Discrimination related to pregnancy and related conditions, including termination of pregnancy, in health programs and activities is so pervasive, takes such varied forms, and is so volatile in the wake of *Dobbs*, that failing to codify some of its most prevalent forms will directly undermine efforts to implement Proposed §§ 92.206 and 92.101. While we welcome additional guidance with hypotheticals of how this discrimination can play out in various contexts, we believe that simply leaving this issue to guidance, or to the preamble of the final rule, is insufficient. We urge HHS to insert provisions that cover the following three forms of discrimination into Proposed § 92.206(b) and recommend specific text at the end of our comments on this subsection.

First, HHS should include a provision that clarifies that covered entities are prohibited from denying or limiting services based on pregnancy or related conditions, including termination of pregnancy, contraception, miscarriage management, assisted reproduction (including fertility care), pregnancy-related services, or other health services.[229] This provision should also clarify that they cannot deny or limit a health care professional's ability to provide these services based on pregnancy or related

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[228] 87 Fed. Reg. 47868.

[229] We recommend that HHS use the term "pregnancy-related services" rather than "maternity care" in Proposed §§ 92.206 and 92.207 to align with the terminology used in the Medicaid Act and implementing regulations. Assisted reproduction (AR) refers to treatments, interventions, or procedures that are intended to cause or assist in causing pregnancy through means other than by sexual intercourse. One well-known technology is in vitro fertilization (IVF) in which mature oocytes are removed from the ovary and fertilized with sperm in a laboratory, and the resulting embryo is introduced into the uterus. This term includes but is broader than fertility care alone. *See* Liz McCaman Taylor et al., Nat'l Health L. Prog., *NHeLP Principles on Assisted Reproduction* (2021), https://healthlaw.org/resource/nhelp-principles-on-assisted-reproduction.

conditions. For years, anti-abortion pharmacists have often refused to fill prescriptions for emergency contraception based on a debunked claim that it "prevents implantation."[230] Research also shows that providers may block individuals from accessing assisted reproduction based on assumptions or biases about who can or deserves to be a parent or who wants or deserves assisted reproduction. For example, women of color "have reported that some physicians brush off their fertility concerns, assume they can get pregnant easily, emphasize birth control over procreation, and may dissuade them from having children."[231]

Clarifying that § 1557's protections against sex discrimination include denying or limiting services, or a health professional's ability to provide such services, based on pregnancy is especially crucial following *Dobbs*. As we discussed in our comments on Proposed § 92.101, more and more states are banning or severely restricting abortions. *Dobbs* has also provoked more and more states to consider severe restrictions and bans on additional reproductive and sexual health services, such as contraception. This landscape makes it all the more important that the final rule clarify protections against sex discrimination related to these services. Because discrimination related to pregnancy or related conditions can also incite covered entities to deny or limit access to other services, we believe this provision should encompass other services as well.

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[230] In NHeLP's experience, it is this debunked argument—that emergency contraception blocks implantation—rather than the reasons in HHS's recent guidance to pharmacies, that pharmacists most often provide when they refuse to fill prescriptions. *See, e.g.*, *Belief That Emergency Contraception Blocks Implantation Not Supported by Science, Investigation Finds*, NAT'L PARTNERSHIP FOR WOMEN & FAMILIES, Jun. 6, 2012, http://go.nationalpartnership.org/site/News2?abbr=daily2_&page=NewsArticle&id=33841; HHS, *Guidance to Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services* (Jul. 13, 2022), https://www.hhs.gov/about/news/2022/07/13/hhs-issues-guidance-nations-retail-pharmacies-clarifying-their-obligations-ensure-access-comprehensive-reproductive-health-care-services.html (hereinafter HHS Guidance to Pharmacies).

[231] Ethics Comm., Am. Soc'y Reproductive Medicine, *Disparities in Access to Effective Treatment for Infertility in the United States: An Ethics Committee Opinion*, 116 FERTILITY & STERILITY 54, 57 (2021), https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities_in_access_to_effective_treatment_for_infertility_in_the_us-pdfmembers.pdf; *see also id.* (discussing the various inequitable barriers to fertility care).

Second, HHS must codify a provision clarifying that § 1557 prohibits denials or limitations on services based on an individual's reproductive or sexual health decisions or history, including termination of pregnancy, miscarriage, or adverse pregnancy outcome. U.S. culture continues to largely stigmatize reproductive or sexual health decisions or history, even though those decisions, such as abortions, and histories, such as miscarriage, are normal. For example, providers have refused care to people seeking hysterectomies or excisions to help remedy chronic pain caused by endometriosis based on their discriminatory beliefs that their patients are making the "wrong choice" and will want to have children one day.[232] Protections against discriminatory limitations on or denials of health services based on an individual's reproductive and sexual health decisions and history are especially critical following *Dobbs*. Some anti-abortion health professionals may interpret this decision as affirmation for their discriminatory beliefs about individuals' reproductive or sexual health decisions or history. Of note, we do not think that the language of this provision should be limited to reproductive or sexual "health **care** decisions or histories," (emphasis added) as covered entities also discriminate based on reproductive and sexual health histories such as past experiences with sexual violence, which exist beyond the realm of services. Include "care" here could limit how covered entities understand this form of discrimination.

Third, HHS must include sex discrimination related to pregnancy or related conditions for people who need access to treatments or medications for disabilities and emergency medical conditions. When the Supreme Court overturned the constitutional right to abortion in *Dobbs*, it provoked covered entities to deny and erect new barriers to medications and treatments that can prevent, cause complications to, or end pregnancies. For example, pharmacies are increasingly refusing to fill or creating burdensome requirements before they will fill prescriptions for methotrexate, which is regularly used to treat cancer and autoimmune conditions.[233] Some pharmacies, such

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[232] Anne Branigin, *Choosing Between Not Having Kids or Pain: An Endometriosis Case is Sparking Outrage*, THE LILY, Apr. 20, 2021, https://www.thelily.com/choosing-between-children-and-a-lifetime-of-pain-a-endometriosis-case-in-the-uk-is-sparking-outrage.

[233] *See, e.g.*, Jamie Ducharme, *Abortion Restrictions May Be Making It Harder for Patients to Get a Cancer and Arthritis Drug*, TIME, Jul. 6, 2022, https://time.com/6194179/abortion-restrictions-methotrexate-cancer-arthritis/; Ian Millhiser, *Can Pharmacists Refuse to Fill Prescriptions for Drugs That Can Be Used in Abortions?*, VOX, Jul. 15, 2022, https://www.vox.com/23207949/supreme-court-abortion-methotrexate-prescription-pharmacist-refuse; Charlotte Huff, *New Abortion Laws Jeopardize Cancer Treatment for Pregnant Patients*,

as CVS Health, are asking pharmacists to verify that prescriptions will not be used to end pregnancies.[234] Verification requirements can unduly delay individuals' access to crucial and potentially life-saving care, compromising cancer treatment or subjecting people to painful and potentially dangerous flare ups of chronic health conditions.[235] Outright refusals to fill prescriptions also cause undue delays in access to care and can particularly harm individuals who live in rural or other isolated communities with one or very limited pharmacy options. While we appreciate HHS's guidance to pharmacies on July 13, 2022, we urge the agency to specifically include a new provision in Proposed § 92.206(b) that clarifies that § 1557 prohibits the underlying form of sex discrimination, which is much broader.[236]

Moreover, this additional provision must clarify that denying an individual access to stabilizing treatments required by EMTALA based on pregnancy or related conditions, including termination of pregnancy, violates § 1557. Per HHS guidance and the preamble to this Proposed Rule, covered entities are required to provide stabilizing treatment for pregnant individuals' emergency medical conditions under EMTALA.[237] This includes medications such as mifepristone or methotrexate for conditions such as ectopic pregnancy, complications of pregnancy loss, and severe preeclampsia when these medications are the necessary stabilizing treatment.[238] Nevertheless, some hospitals in states that have banned abortion are denying access to stabilizing treatments for emergency conditions as defined under EMTALA.[239]

Salon, Sept. 19, 2022, https://www.salon.com/2022/09/19/new-abortion-laws-jeopardize-cancer-treatment-for-pregnant-patients_partner/.

[234] *See, e.g.*, Annie Burky, *Backlash Against CVS, Walgreens Raises Questions About Role Of Retail in Post-Dobbs World*, Fierce Healthcare, Sept. 1, 2022, https://www.fiercehealthcare.com/retail/boycottcvs-draws-reproductive-rights-twitters-regarding-abortion-inducing-medication; Tom Murphy, *CVS Seeks Verification on Drugs With Possible Abortion Use*, Boston.com, Jul. 21, 2022, https://www.vox.com/23207949/supreme-court-abortion-methotrexate-prescription-pharmacist-refuse.

[235] *Id*.

[236] *See* HHS Guidance to Pharmacies, *supra* note 230.

[237] *See, e.g.*, Letter from Xavier Becerra, *supra* note 176.

[238] *See e.g*., Timothy S. Jost, *What Happens When Federal Laws to Provide Emergency Care Clash with State Abortion Laws?*, Commonwealth Fund Blog (Sep. 8, 2022), https://www.commonwealthfund.org/blog/2022/what-happens-when-federal-laws-provide-emergency-care-clash-state-abortion-laws.

[239] *Id*.

We are concerned that without adequate clarity in the final regulatory text, covered entities will only increasingly subject individuals to discriminatory denials of and barriers to the vast array of medications and treatments prescribed for chronic or emergency conditions because those services happen to prevent, cause complications to, or end pregnancies or fertility.

In addition to these amendments to clarify protections related to pregnancy or related conditions, including termination of pregnancy, given the long history of discrimination against and exclusion of LGBTQI+ people, HHS must continue to clarify and build on § 1557's protections to address all forms of sex discrimination. Notably, despite these protections, Transgender adults still experience barriers to care, such as difficulty finding providers who have even minimal experience with treating Gender Diverse patients, waiting outrageous lengths of time to get a consultation with a provider, or traveling significant distances to see a provider.[240] Section 1557 requires more from covered entities. Proposed § 92.206(b) clarifies that hospital staff cannot misgender a Transgender man as he recovers from a hysterectomy procedure based on their biased assumption that every patient in the OBGYN department is a cisgender woman. This subsection will help protect a Transgender man calling his primary care provider's office to access periodic STI testing offered to cisgender women patients from having to explain his gender identity and sex assigned at birth when the office already has that information in its records.

The reality is that binary spaces exist in almost every corner of society, and especially in health care. Thus, these protections are particularly important to ensure that Non-Binary people have equal access to health care services.[241] Health care programs and

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[240] Wyatt Koma et al., 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; Ella Vermeir et al., *Improving Healthcare Providers' Interactions with Trans Patients: Recommendations to Promote Cultural Competence*, 14 HEALTH POL'Y 11 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147364; Sara Heath, *Provider Knowledge Blocks Access to Care for Transgender Patients*, PATIENT ENGAGEMENT HIT, Mar. 9, 2022, https://patientengagementhit.com/news/provider-knowledge-blocks-access-to-care-for-transgender-patients.

[241] Beyond Binary Legal & Harvard Law School LGBTQ+ Advocacy Clinic, *How Federal Agencies Can Ensure Nondiscrimination and Advance Equity for Nonbinary and Gender Nonconforming People* 2-3 (2022),

activities regularly rationalize differential or unequal treatment of Non-Binary patients in their absence of a gender neutral space (*e.g.*, bathrooms, inpatient hospital rooms, intake forms). Section 1557 requires them to do more. For example, this provision would protect patients from provider refusals to use inclusive language when referring to genitals or other sex characteristics when administering reproductive and sexual health services and, instead, referring to body parts as “female” or “male” body parts. We commend HHS for recognizing in Proposed § 92.206(b) the unique forms of discrimination experienced by all LGBTQI+ populations. We ask that HHS swiftly finalize and enforce these protections robustly.

i. Proposed § 92.206(b)(1)

We support HHS’s decision to base this provision off of the text of the 2016 Final Rule. We note that Proposed § 92.206(b)(1) differs in that it does not explicitly include the word “transgender”. This change acknowledges that discriminatory treatment is not the exclusive experience of LGBTQI+ people, while still recognizing that sex-based discrimination disproportionately impacts the LGBTQI+ community. Indeed, LGBTQI+ people report experiencing discrimination in health care at higher rates than heterosexual and/or cisgender individuals.[242] However, anyone regardless of sex can experience transphobia, homophobia, biphobia, and other forms of sex discrimination in health care settings. We appreciate that the proposed language reflects this reality and focuses on the purpose at hand: protecting equal access to health care services for all individuals.

While the medical landscape for LGBTQI+ people has advanced, there are gaping holes in medical research on LGBTQI+ health and data. The medical field’s lack of attention to the LGBTQI+ community translates into disproportionate health outcomes among LGBTQI+ patients. Many LGBTQI+ individuals face harmful biases and harassment, or outright refusals of care, in health care settings. As is true for many underserved populations protected by § 1557, many LGBTQI+ patients must act as their own expert and advocate in their care. More importantly, these institutional and systemic gaps deprive LGBTQI+ patients of quality, responsive, compassionate health care, which harms and negatively impacts their lives. In a 2020 survey, forty-seven percent of

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https://static1.squarespace.com/static/5e5821d555aa43474493b45d/t/62fa7e56157431683154d0cf/1660583511170/2022.08.15+federal+agencies+nonbinary+equity.pdf.

[242] Sharita Gruberg et al., Ctr. Am. Prog., *The State of the LGBTQ Community in 2020* (2020), https://www.americanprogress.org/article/state-lgbtq-community-2020.

Transgender people reported not visiting the doctor when they needed to because they were afraid of encountering discrimination.[243] In the same survey, almost twenty percent of Transgender participants reported that their provider refused to see them at all because of their actual or perceived gender identity.[244] This number increased to almost thirty percent for Transgender participants of color.[245] In fact, many Transgender patients are not out to their providers about their gender identity.[246] Even in instances where providers are not hostile to LGBTQI+ individuals, discrimination may still surface. For example, if a provider assumes a patient is heterosexual and/or cisgender when the patient actually identifies as Gay or Bisexual, and Transgender, the provider is jeopardizing the quality of the patient's care. For example, a provider who assumes that a Transgender man has only cisgender female partners may fail to provide that man with contraceptive and pregnancy-related services he needs. Therefore, it is imperative that the § 1557 regulations prohibit sex-based discrimination to promote better health outcomes and equity.

These types of inequities trickle into other areas of health care. So often Transgender, Non-Binary and Gender Diverse patients are treated as if their health goals are confined to their gender identity and sex characteristics, even though some Transgender, Non-Binary and Gender Diverse individuals do not seek medical intervention to affirm their gender identity. Treatment options for gender-affirming services are often presented as mutually exclusive to other care, including for other reproductive and sexual health services. For example, a provider for a Non-Binary person seeking a prescription for testosterone for gender-affirming hormone therapy must adequately explain the treatment options, risks, and side effects for this treatment, including the potential impacts on the patient's ability to give birth. However, some providers still believe, and incorrectly advise patients, that testosterone is a contraceptive, and fail to give their

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[243] *See, e.g., id.*; Genny Beemyn, *Transgender History in the United States* (2d. Ed. 2022), https://www.umass.edu/stonewall/sites/default/files/Infoforandabout/transpeople/genny_beemyn_transgender_history_in_the_united_states.pdf.

[244] Gruberg et al., *supra* note 242.

[245] *Id.*

[246] *See* Sandy E. James et al., Nat'l. Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* 91 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf (31% of Transgender participants reported that none of their providers knew their gender identity).

patients appropriate advice and information about their ability to conceive and contraceptive options.[247]

Many providers also fail to frame discussions about gender-affirming hormone therapy and family planning services in ways that recognize and discuss the nuanced and human needs and desires of their Transgender, Non-Binary and Gender Diverse patients who want to give birth *and* move forward with gender-affirming hormone treatment, while cisgender patients seeking treatment that may adversely impact their ability to get pregnant are offered family planning support and information. This bias harms and dehumanizes Transgender, Non-Binary and Gender Diverse patients' experiences and their abilities to have families.[248] Even in instances where providers are educated about LGBTQI+ health issues, often LGBTQI+ patients are seen in the narrow context of their sexual orientation and/or gender identity. LGBTQI+ patients are much more than their sexual orientation or gender identity and need access to care that is more directly related to each identity, and some care that is not. The language in this provision establishes a strong standard to makes clear that covered entities cannot deny or limit access to health services based on sex.

For example, under Proposed § 92.206(b)(1):

- A mental health provider could not deny access to family therapy because one of the family members is a Transgender woman.

- A general practitioner who routinely provides contraceptive counseling at annual visits must offer that counseling to a Bisexual woman patient regardless of their assumptions that such counseling is inapplicable based on her sexual orientation.

- A Non-Binary person can access medically necessary gender-affirming chest surgery without requiring that the patient identify as male or female.

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[247] Alexis Light et al., *Family Planning and Contraception Use in Transgender Men* (2018), https://pubmed.ncbi.nlm.nih.gov/29944875/.

[248] Danielle Boudreau et al., *Contraception Care for Transmasculine Individuals on Testosterone Therapy*, 64 J. MIDWIFRY WOMEN'S HEALTH 395 (2019); *see also* Heidi Moseson et al., *Pregnancy Intentions and Outcomes Among Transgender, Nonbinary, and Gender-Expansive People Assigned Female or Intersex at Birth in the United States: Results from a National, Quantitative Survey*, 17 INTERNAT'L J. TRANS. HEALTH 30 (2021).

- An endocrinologist advising a Transgender man about starting testosterone must inform him about potential implications for fertility, ask him about his family planning goals, and counsel him accordingly.

- A covered entity that routinely provides gynecological care could not deny an individual a pelvic exam because they are a Transgender man.

We strongly support HHS's clarification in this provision (as well as Proposed § 92.206(b)(2) and later in § 92.207(b)(3)) that sex discrimination includes discrimination on the basis of sex at birth, recorded gender, or gender identity. The proposed language is consistent with the Supreme Court's holding in *Bostock*; discrimination on the basis of sex encompasses differential treatment on account of someone's physical sex characteristics and/or the expectations attached to those characteristics. If an insurer denies or limits coverage because of an individual's recorded sex or gender, the gender identity associated with that individual's recorded sex or gender, or the individual's perceived gender identity, the insurer discriminates on the basis of sex.

This change from the 2020 Proposed Rule better aligns with developments in federal law and medical expertise, addresses known and ongoing discriminatory actions, and advances the spirit and purpose of § 1557. Increased awareness of the lives and experiences of Transgender and Gender Diverse individuals has resulted in profound scientific developments in transgender medicine and gender-affirming care. The World Professional Association of Transgender Health has published eight versions of its Standards of Care since 1979, which have now been endorsed by the American Academy of Pediatrics, the American Medical Association, the American Psychiatric Association, the American Academy of Child & Adolescent Psychiatry, and the HHS Office of Population Affairs.[249] Governments have adopted sex classifications inclusive of transgender and gender diverse individuals, such as procedures for legally changing gender markers on identity documents and the addition of "X" to denote Non-Binary

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[249] U.S. Professional Association for Transgender Health (US PATH), *USPATH Position Statement on Legislative and Executive Actions Regarding the Medical Care of Transgender Youth* (2022), https://www.wpath.org/media/cms/Documents/USPATH/2022/With%20Date%20Position%20Statement%20Anti%20Trans%20Leg%20USPATH%20Apr%2022%202022.pdf.

genders.[250] Courts, including most federal courts before *Bostock,* affirmed the logical conclusion that discrimination against people who are Transgender, Non-Binary, or Gender Diverse is on account of that person's sex.[251] For decades, our society has affirmed the relationship of gender identity to sex. Therefore, it is reasonable and necessary that this rule should align its definitions of sex discrimination with the medical and social understandings of sex as well.

ii. Proposed § 92.206(b)(2)

We also strongly support the language in Proposed § 92.206(b)(2) prohibiting covered entities from denying or limiting a health care professional's ability to provide care based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded when doing so excludes the individual from participation in, denies them the benefits of, or otherwise subjects them to discrimination on the basis of sex. It is imperative that health care professionals provide necessary, responsive, well-established, evidence-based, and clinically appropriate treatment within their scope of practice and expertise.

At present, hundreds of bills have been introduced in state legislatures across the U.S. targeting LGBTQI+ individuals in almost every aspect of daily living, including accessing health care, obtaining identity documents, using public facilities, restricting inclusive learning, and participating in sports.[252] A large swath of these legislative proposals include attempts, some of which have been enacted, to restrict access to gender-affirming care, especially for youth.[253] Some of these state legislative efforts seek to

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[250] Movement Advancement Project, *Equality Maps: Identity Document Laws and Policies*, https://www.lgbtmap.org/equality-maps/identity_document_laws (last visited Aug. 30, 2022); Lambda Legal, *X Gender Markers By State*, https://www.lambdalegal.org/map/x-markers (last visited Aug. 30, 2022).

[251] Movement Advancement Project, *Equality Maps: Federal Court Decisions on Sex Discrimination, Sexual Orientation, and Gender Identity*, https://www.lgbtmap.org/equality-maps/federal_court_decisions (last visited Aug. 30, 2022); Nat'l Ctr. for Transgender Equality, *Federal Case Law on Transgender People and Discrimination*, https://transequality.org/federal-case-law-on-transgender-people-and-discrimination (last visited Aug. 30, 2022).

[252] ACLU, *Legislation Affecting LGBTQ Rights Across the Country 2021* (last updated Dec. 12, 2021), https://www.aclu.org/legislation-affecting-lgbtq-rights-across-country-2021 .

[253] *Id.;* Helen Santoro, *Advocating for Transgender and Nonbinary Youths*, AM. PSYCH. ASSOC., July 1, 2022, https://www.apa.org/monitor/2022/07/advocating-transgender-nonbinary-youths; *see also* Trans Formation Project, Legislative Tracker, https://www.transformationsproject.org/legislation (last visited Aug. 29, 2022).

restrict or outright ban health care providers from providing safe, effective, and life-saving treatment to LGBTQI+ patients with punishment including criminalization of providers.[254] These discriminatory state bans not only stigmatize and impose an incredible chilling effect on LGBTQI+ patients and strain the patient-provider relationship, but also undermine scientific and evidence-based practices. Banning or delaying care that is otherwise clinically appropriate not only places inappropriate limitations on providers' ability to care for their patients, but it ultimately exacerbates symptoms and stressors of LGBTQI+ patients.[255] Proposed § 92.206(b)(2) aims to ensure that specialists and providers who interface with LGBTQI+ patients every day do not experience retaliation for providing care due to prejudices held by covered entities.

We appreciate that this provision seeks to align § 1557's application with Title VI's prohibition on discrimination where it has the secondary effect on a person's ability to participate in/or receive the benefits of programs and services by covered entities.[256] This language will safeguard health providers' ability to administer clinically appropriate treatment for LGBTQI+ individuals. For example, it will ensure that a provider can prescribe clinically appropriate puberty-delaying medication to a Transgender minor without fear of losing their license or employment. Currently, some providers have halted providing gender-affirming services altogether, due to very real fears of retaliation from state attempts to restrict access.[257] This has resulted in cancellations for

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[254] ACLU*, supra* note 252; *see also* Kerith J. Conron et al., UCLA School of Law, *Prohibiting Gender-Affirming Medical Care for Youth* (2022), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Youth-Health-Bans-Mar-2022.pdf. Due to legislative efforts among the current 15 states to restrict or ban gender-affirming care for Transgender youth, more than 58,000 youth and young adults risk losing access to gender-affirming care. *See id.*

[255] Abigail Coursolle et al., Nat'l Health L. Prog., *Gender-Affirming Care for Youth is Good Health Care* (2021), https://healthlaw.org/gender-affirming-care-for-youth-is-good-health-care/.

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

[257] Anne Branigin, *In Texas, the Nation's Largest Children's Hospital is Halting Gender-Affirming Care for Trans Youths,* WASHINGTON POST, Mar. 8, 2022, https://www.washingtonpost.com/lifestyle/2022/03/08/texas-childrens-hospital-stops-gender-affirming-care-trans-youth; Christopher O'Donnell, *Some Hospitals Stopping Treatment for Transgender Youth in Florida*, TAMPA BAY TIMES, Aug. 29, 2022, https://www.tampabay.com/news/2022/08/29/floridas-transgender-debate-affecting-treatment-surgeries/; Shannon Bond, *Children's Hospitals are the Latest Target of Anti-LGBTQ Harassment,* NAT'L PUB. RADIO, Aug. 26, 2022, https://www.npr.org/2022/08/26/1119634878/childrens-hospitals-are-the-latest-target-of-anti-lgbtq-harassment.

scheduled gender-affirming care procedures, restrictions by providers who are not accepting TGI patients, and patients and their families scrambling to seek gender-affirming care services elsewhere.

These barriers make care more time-consuming and expensive to access. For many individuals, it causes incredible delays in obtaining care because of the lack of providers knowledgeable in LGBTQI+ care. For example, some Transgender and Gender Diverse people wait several years for a medically necessary surgery. Some do not receive the preventive services and medically necessary care at all.[258] Thus, we support HHS's inclusion of protections for health care professionals who are qualified and wish to provide affirming health services for LGBTQI+ people.

iii. Proposed § 92.206(b)(3)

a. Proposed § 92.206(b)(3) protects Transgender, Non-Binary, and Gender Diverse People

While we appreciate that under Proposed § 92.206(b)(3), treatments for conditions specific to sex characteristics could not be denied or restricted based on sex, more specificity is necessary. It is not enough that providers simply provide care that is specific to a patient's sex regardless of how they identify; providers must administer such care in a respectful, dignified, and culturally competent manner. Failure to do so causes harm to Transgender, Non-Binary, and Gender-Diverse individuals that effectively others them and amounts to differential and separate treatment. Such alienating behavior includes routine misgendering of patients, unwanted isolation, compromised privacy, and harassment. The text of this provision should also rise to standards of impermissible harm even if they fall short of actually preventing a patient from participating in a health program or activity that is consistent with their gender identity. Even binary Transgender patients are misgendered by hospital staff, even if they are perceived as cisgender and/or their pronouns and gender identity are documented in their Electronic Health Records (EHRs) simply because they are getting a sex-specific procedure. For example, a Transgender man recovering in the hospital after completing a hysterectomy may still be misgendered simply because he is in the OBGYN facility of the hospital, because the hospital staff are not referencing his EHRs consistently when attending to his care.

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[258] *See e.g.*, Vermeir, *supra* note 24 at 13; Heath, *supra* note 240.

We support the language that explains that harm that is more than *de minimis* may "include any adverse effect on a person's equal access to or participation in" a health program or activity based on sex. We appreciate that the language in the provision continues to explain that harm that is more than *de minimis* may include policies that prevent participation in a health program or activity "consistent with the individual's gender identity".

While we support his standard, including the Proposed Rule's inclusion of the *Bostock* reasoning to support sex-based discrimination, it currently leaves open key questions about its application to Non-Binary and other Gender-Expansive individuals and should be clarified. For example, the preamble reasons that assigning patients to dual-occupancy rooms in hospitals on the basis of sex is a permissible sex-based distinction that does not amount to a necessary threshold of *de minimis* harm.[259] However, this example glosses over the fact that most public spaces reinforce binary identities, including hospitals, and therefore do not accommodate Non-Binary and Gender-Expansive individuals. Therefore, the final rule needs to include language that specifies when sex-based distinctions do arise in settings where it may be unavoidable (*e.g.* binary bathrooms), that Non-Binary and Gender-Expansive individuals are entitled to participate in the way they feel most comfortable at any given time. As such, we propose adding language into § 92.206(b)(3) (*see* Recommendations below).

b. <u>Proposed § 92.206(b)(3) will ensure access to necessary care for pregnancy or related conditions</u>

As HHS has recognized through various initiatives and in the preamble to the Proposed Rule, the U.S. continues to grapple with a severe maternal morbidity and mortality epidemic. The U.S. has the worst maternal mortality rate of any high-income country and from 2000–2020, was one of only two countries to report a significant increase in their maternal mortality ratio.[260] From 2018–2020, severe maternal morbidity rates increased among all women by about 9 percent. This trend held true for all women, suggesting that childbirth complications are increasing regardless of whether a person

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[259] 87 Fed. Reg. 47866.

[260] See Eugene Declercq & Laurie Zephyrin, Commonwealth Fund, *Maternal Mortality in the United States: A Primer* 1 (2020), https://www.commonwealthfund.org/publications/issue-brief-report/2020/dec/maternal-mortality-united-states-primer.

is covered by Medicaid or commercial insurance.[261] These inequities continue to harm people well into the postpartum period. More than half of U.S. maternal deaths occur after the date of delivery, and twelve percent happen between forty-three and 365 days postpartum.[262] Because of structural racism, Black and Indigenous women and birthing people develop and die from pregnancy-related complications at exponentially higher rates than white people.[263] The vast majority of these deaths are preventable.[264]

These inequities are not random. Intersecting racism, sexism, and often additional forms of discrimination are entrenched in every facet of our society. Pregnant and postpartum Black, Indigenous, Latina/x, Asian American and Pacific Islander, and all people of color, and others who live at the intersections of § 1557's protected classes, are often subjected to discrimination in health care throughout pregnancy and the postpartum period. For example, in a 2019 national survey, one in six women reported mistreatment during childbirth.[265] Respondents reported incidents such as health care providers and staff shouting at, scolding, or ignoring their requests for care. Indigenous, Hispanic, and Black women reported experiencing this discrimination at much higher rates than white women. In a 2018 California survey, Black, Asian, and Pacific Islander women who gave birth in hospitals reported higher rates of unfair treatment, harsh language, and rough handling than white women.[266]

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[261] Blue Cross Blue Shield, *Racial and Ethnic Disparities in Maternal Health*, (Sept. 21, 2022), https://www.bcbs.com/the-health-of-america/reports/racial-and-ethnic-disparities-maternal-health.

[262] *See* Declercq & Zephyrin, *supra* note 260.

[263] Ctrs. for Disease Control and Prevention (CDC), Pregnancy Mortality Surveillance System, https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm#trends (last visited Dec. 1, 2021) (finding pregnancy-related mortality ratios over three and two times higher for non-Hispanic Black women and non-Hispanic American Indian or Alaska Native women, respectively, than their non-Hispanic white counterparts).

[264] Susannah Trost, CDC, *Pregnancy-Related Deaths: Data from Maternal Mortality Review Comittees in 36 States, 2017–2019*, https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html (last visited September 20, 2022).

[265] Saraswathi Vedam et al., *The Giving Voice to Mothers Study: Inequity and Mistreatment During Pregnancy and Childbirth in the United States*, 16 REPRODUCTIVE HEALTH 77 (2019).

[266] Carol Sakala et al., National Partnership for Women & Families, *Listening to Mothers in California: A Population-Based Survey of Women's Childbearing Experiences, Full Survey Report*, 64-65 (2018) https://www.chcf.org/wp-content/uploads/2018/09/ListeningMothersCAFullSurveyReport2018.pdf.

Section 1557 is an essential but underutilized tool for addressing discrimination in pregnancy-related services. Clarifying protections against related sex discrimination in health programs and activities could help improve health outcomes, promote racial health equity, and save lives. To clarify covered entities' related obligations, HHS must amend Proposed § 92.206(b)(3). This provision should clarify that covered entities must not 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 policies or practices that subject people to rough handling, harsh language, undertreatment of pain or pregnancy-related conditions, or other discriminatory mistreatment during childbirth or the prenatal or postpartum periods. We recommend specific amendments at the end of our comments on Proposed § 92.206.

iv. Proposed § 92.206(b)(4)

a. Proposed § 92.206(b)(4) is necessary to ensure access to Gender-Affirming Care

We strongly support Proposed § 92.206(b)(4)'s prohibition on blanket denials or restrictions to gender-affirming care on the basis of sex. We also support the specific discriminatory actions that covered entities may not take identified in the preamble.[267] This explicit language will protect equal access to health services, as well as prevent covered entities from targeting gender-affirming care services in conflict with established scientific and medical standards. We commend HHS for explicitly stating that gender-affirming care services must be protected under the relevant clinical guidelines regardless of the language a patient uses to describe their gender identity. The proposed language acknowledges that gender is specific to the individual. What defines a service as "gender-affirming" does not look the same for everyone regardless of their sex.

While we welcome the inclusive and non-prescriptive approach in the proposed language, it is not appropriate to *only* assess access to gender-affirming care in comparison to standards applied to cisgender people. Proposed § 92.206(b)(4) prohibits denials or limitations on gender-affirming services that a covered entity "would provide to an individual for other purposes" if the denial or limitation is based on sex. While individuals of any gender identity can technically experience gender dysphoria, such a comparison cannot always be consistently applied because such services may be

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[267] *See* 87 Fed. Reg. 47867.

sought for an entirely different purpose that cannot be compared to gender dysphoria. For example, a Transgender woman seeking gender-affirming rhinoplasty should not be granted the procedure because in some instances, a cisgender woman might need medically necessary rhinoplasty. Rather, medical necessity for gender-affirming rhinoplasty should be assessed because the patient has gender dysphoria, which is a diagnosis that can be successfully treated via gender-affirming rhinoplasty. Gender dysphoria is a valid and strong diagnosis on its own for covered entities to determine appropriate treatment for TGI patients. As such, we propose striking language from § 92.206(b)(4) to remove comparator language from the provision (see Recommendations below).

b. <u>Proposed § 92.206(b)(4) will ensure access to necessary care for pregnancy or related conditions</u>

Despite § 1557's clear prohibition of sex discrimination in health care, discrimination in access to infertility diagnosis, treatment, and services such as assisted reproductive technology persist. As we discuss in our comments on additional gaps below, discrimination related to fertility care can take many forms in health programs and activities, but denials or limitations on access are particularly pervasive for LGBTQI+ people. Thus, HHS should explicitly clarify that this is prohibited conduct under § 92.206(b)(4). Because people also often experience other blanket denials (*e.g.*, for other reproductive and sexual health care) on the basis of sex assigned at birth, gender identity, or gender otherwise recorded, we also recommend the addition of "or any health services." Again, we recommend specific amendments at the end of our comments on Proposed § 92.206.

<u>RECOMMENDATION</u>: We urge HHS to amend proposed § 92.206(b) as follows:

(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 but not limited to one that:***
  (i) ***Prevents an individual from participating in a health program or activity consistent with the individual's gender identity;***
  (ii) Prevents an individual from participating in a manner they feel most comfortable at any given time, if none of the available health programs or activities are consistent with their gender identity; or

(iii) Subjects an individual to rough handling, harsh language, inadequate care for pain or other pregnancy-related conditions, or other mistreatment during childbirth or the prenatal or postpartum periods**;**

(4) Deny or limit health services sought for purpose of gender transition or other gender-affirming care***, assisted reproduction including fertility services, or any other health services***~~***, 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.

(5) Deny or limit services, or a health care professional's ability to provide services, on the basis of pregnancy or related conditions, including termination of pregnancy, contraception, miscarriage management, assisted reproduction including fertility services, pregnancy-related services, or other health services;

(6) Deny or limit services based on a person's reproductive or sexual health decisions or history, including termination of pregnancy, miscarriage, or adverse pregnancy outcome; and

(7) Deny or limit services, or a health care professional's ability to provide services, because the services could prevent, cause complications to, or end fertility or pregnancies, including medications or treatments for disabilities or emergency medical conditions under 42 U.S.C. § 1395dd.

In addition, HHS should clarify that § 1557 preempts any state or local law restricting access to gender-affirming care, abortions, termination of pregnancy, or other health services.

C. Proposed § 92.206(c)

As we discussed in our comments on Proposed § 92.206(b), we strongly support HHS's proposed language to clarify that blanket denials or restrictions to gender-affirming care on the basis of a person's sex are prohibited. The language of Proposed § 92.206(c) recognizes and protects covered entities who may not provide certain services within their scope of practice as non-discriminatory.

We also commend this provision's strong language clarifying that § 1557 expressly prohibits covered entities from imposing their individual beliefs that gender-affirming care can never be beneficial. Covered entities cannot cite beliefs that deviate from established scientific and medical standards as justification for denying the provision of gender-affirming care services. It is imperative that advancements in established medicine are valued to inform the standards of care for Transgender and Gender-Diverse populations.

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

We welcome HHS's restoration of § 1557 regulations expressly prohibiting discriminatory benefit design and marketing. The 2020 Final Rule eliminated, with little explanation, important regulatory provisions that clarified the nondiscrimination obligations of insurers and other covered entities. We strongly support the 2022 Proposed Rule that firmly establishes nondiscrimination requirements in health insurance coverage and other health-related coverage and administration.

However, we urge HHS to further explain and clarify discrimination through benefit design and marketing, as well as how HHS (and OCR) will coordinate with other federal and state agencies to monitor compliance and enforce § 1557 protections.

The ACA prohibits many long-standing discriminatory practices by health insurers, including requiring guaranteed issue of coverage in the individual and small group health insurance markets so that no one can be denied health insurance due to a preexisting condition.[268] The ACA also prohibits discrimination against individual participants and beneficiaries based on health status or medical condition, and it prevents insurers from imposing annual or lifetime limits on benefits.[269]

Before the ACA, health insurers routinely discriminated against people with pre-existing conditions, including persons with disabilities and those with chronic illness, by charging them exorbitant premiums, excluding coverage for their conditions, or refusing to provide health coverage at all. Although the ACA made these practices unlawful, some insurers still seek to discriminate through benefit design and marketing.

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[268] 42 U.S.C. § 300gg-1.

[269] 42 U.S.C. § 300gg-11.

The 2016 Final Rule made clear that § 1557 prohibits "marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy."[270] In guidance, HHS provided examples of practices that would contravene § 1557 and this regulation. Plans that, for example, "cover bariatric surgery in adults but exclude such coverage for adults with particular developmental disabilities place[e] most or all drugs that treat a specific condition on the highest cost tiers or exclude bone marrow transplants regardless of medical necessity" would run afoul of § 1557, HHS explained.[271]

HHS's 2016 regulation and the 2022 Proposed Rule logically follow the letter and intent of the ACA. Without explicit acknowledgement of, and a resulting prohibition on, discriminatory benefit design, § 1557's nondiscrimination protections would be rendered illusory. By not reaching the structure of a benefit package, a health insurer could always manipulate their benefit design to elude discrimination law, despite maintaining the same discriminatory effects.

For illustration, consider benefits to treat cancer. Without the ACA reaching benefit designs, a health insurer could not deny an individual with cancer enrollment in a QHP or equal access to the treatments, services, and prescription drugs the plan chooses to cover; however, it could exclude from its coverage all cancer-related surgery, chemotherapy, radiation, and post-treatment drugs. It could also limit enrollees to provider networks that fail to include key oncology specialists, thus avoiding coverage of the expensive treatments they may prescribe. For a person with cancer, access to a health plan would be deemed virtually meaningless in the absence of cancer-related coverage.

Insurance companies have used many features of health plan benefit design and delivery to unlawfully deny needed coverage or discourage people with significant or high cost health needs from enrolling in their plans. These include exclusions, cost

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[270] 81 Fed. Reg. 31,471, *codified as* 45 C.F.R. § 92.207.

[271] 81 Fed. Reg. 31,429; *HHS Notice of Benefit and Payment Parameters for 2016*, 80 Fed. Reg. 10,750, 10,822 (Feb. 17, 2015); CMS CCIIO, *QHP Master Review Tools for 2015, Non-Discrimination in Benefit Design* (2015), http://insurance.ohio.gov/Company/Documents/2015_Non-Discriminatory_Benefit_Design_QHP_Standards.pdf.

sharing, formularies, visit limits, provider networks, prior authorization and other utilization management that are arbitrary and not clinically based or appropriate.

The American Academy of Actuaries Committee Health Equity Work Group (HEWG), identified numerous plan design features, including cost sharing, provider networks and service areas, and utilization management, that can lead to reduced access and health disparities among racial and ethnic minority populations and underserved or under-resourced communities.[272]

Health care advocates and researchers have identified several areas where issuers have employed discriminatory practices or benefit design, including:

- Cost sharing
- Medical necessity definitions
- Narrow networks
- Drug formularies
- Adverse tiering
- Benefit substitution
- Utilization management
- Exclusions
- Visit limits
- Waiting periods
- Service areas
- Coercive wellness programs.[273]

Yet many individuals continue to face discrimination on a variety of other factors. Just with regards to gender identity, the following experiences support the need for the provisions in the Proposed Rule:

The Proposed Rule's proposed definition of "health program or activity" includes a state or local health agency. The 2016 rule expressly listed Medicaid, CHIP, and BHP, and HHS seeks comment as to whether the 2022 regulatory language should explicitly list these programs. Individuals' experiences support the inclusion of a state or local health

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[272] American Academy of Actuaries, Health Equity Work Group, *Health Equity from an Actuarial Perspective: Health Plan Benefit Design* (July 2021), https://www.actuary.org/sites/default/files/2021-07/Health_Equity_Benefit_Design_Discussion_Brief_07.2021.pdf. *See also*, Annette V. James, MAAA, FSA, FCA, Chairperson, Health Equity Committee, Presentation to the National Association of Insurance Commissioners (NAIC) Special (EX) Committee on Race and Insurance, Workstream Five (Aug. 23, 2022), https://www.actuary.org/sites/default/files/2022-08/Academy_NAIC_Race_and_Ins_Workstream_5_Presentation_08_23_22.pdf.

[273] Katie Keith, et al., *Nondiscrimination Under the Affordable Care* Act (July 1, 2013). Georgetown University Health Policy Institute, (Dec. 2013), https://ssrn.com/abstract=2362942.

agency. These exclusions occur in Medicaid as well as state employee plans. Examples of both types of exclusions follow.

Examples of coverage exclusions in Medicaid

- In Florida, a 28-year-old transgender man, enrolled in the state's Medicaid program, receives medically necessary hormone therapy to treat his gender dysphoria. He had received this care since 2017, which up until now, Medicaid has always covered. Medicaid also covered the chest surgery he obtained as treatment for his gender dysphoria in April 2022. Florida's newly adopted rule, denying coverage for gender-affirming care to treat gender dysphoria for transgender Medicaid beneficiaries, threatens his access to care. His only source of income is his monthly supplemental security income he receives due to a disability. He cannot afford the medically necessary hormone therapy, which has relieved some of the clinically significant distress underlying his gender dysphoria, without Medicaid covering the treatment.[274]

- A transgender college student, enrolled in Florida's Medicaid program, receives hormone therapy to treat his gender dysphoria which had been covered under Medicaid until now. The state's Medicaid program had already pre-authorized chest surgery as treatment for his gender dysphoria, which he is scheduled to receive in December 2022. The day after hearing that his surgery had been preauthorized, he learned of the newly adopted coverage exclusion. Without Medicaid, he cannot afford to pay for his hormone therapy or his authorized surgery, both of which his medical providers have determined are medically necessary for his health and wellbeing.[275]

- In 2017, Wisconsin's Medicaid program refused to cover chest reconstruction surgery for a transgender man, a surgery which doctors deemed medically necessary as treatment for his gender dysphoria. A state regulation prohibited Medicaid coverage for surgeries or hormone treatments (among other gender

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[274] Complaint at 6, 44-46 ¶¶ 13, 136, 138, 139, 141, 145, *Dekker v. Marstiller*, No. 4:22-cv-00325 (N.D. Fla. Sept. 7, 2022). https://healthlaw.org/wp-content/uploads/2022/09/FILED-Complaint-against-AHCA.pdf.

[275] *Id.,* Complaint at 7, 52-53 ¶¶ 14, 171-72.

affirming care) for transgender individuals even while providing coverage for the same services to address health conditions other than gender dysphoria. This individual's gender dysphoria significantly worsened after the coverage denial. He experienced profound depression and emotional distress, even having occasional thoughts of self-harming behavior to remove his breasts himself and more frequent suicidal thoughts.[276]

- A transgender seventeen-year-old enrolled in Arizona's Medicaid program began to live in accordance with his male gender identity at the age of thirteen. Since that time, he has worn a binder to flatten his chest which helps to alleviate his gender dysphoria, but significantly impedes his ability to function and causes him pain and discomfort. In 2019, his pediatrician and therapist recommended that he obtain male chest reconstruction surgery to further alleviate his gender dysphoria. However, Arizona's Medicaid program refused to cover the surgery due to a state regulation prohibiting Medicaid coverage for "gender reassignment surgeries." The state covers the same surgery to treat other health conditions.[277]

Example of a coverage exclusion in a State Employee Health Plan

- A transgender woman in Wisconsin was blocked from obtaining medically necessary gender affirming care by a categorical exclusion adopted by Wisconsin's health insurance plan for state employees. She could not afford to pay for the gender affirming surgery she needed on her own and suffered emotional distress as a result of the coverage denial.[278]

In the discussion that follows, we will describe some of these practices (see also discussion on § 92.210 Nondiscrimination in the use of clinical algorithms in decision-making and § 92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services). Also, note that discriminatory benefit design is not

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[276] Complaint at 1-2, 18-21 ¶¶ 2-3, 70-79, *Flack v. Wisconsin Dep't of Health Services*, No. 3:18-cv-00309 (W.D. Wis. Apr. 30, 2018) (available from NHeLP).

[277] Complaint at 2-3, 13, 16-17 ¶¶ 4-9, 64, 81-88, *D.H. v. Snyder*, No. 4:20-cv-00335 (D. Ariz. Aug. 6, 2020) (available from NHeLP).

[278] Brief of Nonprofit Civil Rights, Advocacy and Public Interest Organizations as Amicus Curiae at 20, *Kadel v. North Carolina State Health Plan*, No. 20-1409 (4th Cir. Oct. 7, 2020) (available from NHeLP).

exclusive to insurers. PBMs, providers, and other covered entities are continually finding new cost avoidance strategies that may run afoul of § 1557 and other ACA protections.

A. Cost sharing

Ostensibly, cost sharing in the form of deductibles, copays, and coinsurance, can help reduce or eliminate unnecessary utilization of services by transferring some of the cost of care to the enrollee. Although the ACA caps total out of pocket (OOP) expenses for most plans, those caps are still too high and leave many individuals and families with high OOP costs.[279] However, insurance companies and PBMs are increasingly weaponizing cost sharing, disproportionately affecting persons with disabilities, chronic conditions, and other significant health needs.

Coinsurance, in which enrollees must pay a percentage of the cost of a drug or service, is inherently discriminatory, unduly shifting the cost of care onto persons who need it most. The consequences of high cost sharing for those who rely on prescription coverage, such as people living with HIV/AIDS, are well documented. Fewer prescriptions will be filled, leading to disruptions in treatment and worse health outcomes.[280] Gaps in treatment can have deadly consequences for some, including

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[279] The OOP cap is $8,700 for self-only coverage and $17,400 for other than self only for the 2022 benefit year for QHPs sold through the ACA Marketplaces. *See* https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/.

[280] *See e.g.*, Joel F. Farley, *Medicaid Prescription Cost Containment and Schizophrenia*, 48 MED. CARE 440–447 (2010) (finding that aggressive cost-containment policies in Mississippi caused patients to be 4.87% less compliant with antipsychotic treatments, in addition to experiencing 20.5% more 90-day antipsychotic treatment gaps); Teresa B. Gibson et al., *The Effects of Prescript Drug Cost Sharing: A Review of the Evidence*, 11 AM. J. MANAGED CARE 730–40 (2015) (finding that higher levels of prescription drug cost sharing can cause treatment disruptions such as lower levels of treatment adherence, initiation, and continuation, especially for chronically ill patients); Daniel M. Hartung et al., *Impact of a Medicaid Copayment Policy on Prescription Drug and Health Services Utilization in a Fee-for-Service Medicaid Population*, 46 MED. CARE 565–572 (2008) (finding that copay implementation significantly decreased utilization of prescription drugs, especially for patients with diabetes, respiratory diseases, and schizophrenia); Nantana Kaisaeng et al., Carroll, *Out-of-Pocket Costs and Oral Cancer Medication Discontinuation in the Elderly*, 20 J. MANAGED CARE PHARMACY 669–675 (2014) (finding that high out-of-pocket costs cause patients to delay or discontinue their drug therapy); Deliana Kostova & Jared Fox, *Chronic Health Outcomes and Prescription Drug Copayments in*

people living with HIV/AIDS where "even short interruptions of care can threaten health and undermine prevention effects."[281]

The Essential Health Benefits (EHBs) are subject to limitations on patient cost-sharing.[282] Once a patient has hit their out-of-pocket maximum, in-network EHB services must be paid for in full by the health plan. Further, health plans cannot impose an annual or lifetime cap on EHB services, so health plans cannot stop paying once costs reach a certain threshold. Though self-insured and large group plans are not required to cover EHBs, if they do, they must apply cost-sharing protections.[283]

Insurers, through contracts with PBMs, are increasingly adopting a practice whereby they declare certain, high cost drugs as "non-EHB." Plans do not have to apply cost

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Medicaid, 55 MED. CARE 520–527 (2017) (estimating that the drug copayments in Medicaid are associated with an average rise in uncontrolled hypertension and uncontrolled hypercholesterolemia); Sujha Subramanian, *Impact of Medicaid Copayments on Patients With Cancer*, 49 MED. CARE 842–847 (2011) (finding that use of copayments does not decrease overall cost, and can lead to negative consequences such as decreasing the number of days of supply of prescription drugs, reducing use of prescription drugs for patients with multiple comorbidities, increasing emergency room visit, and so on); Samantha Artiga et al., *The Effects of Premium and Cost-Sharing on Low-Income Populations: Updated Review of Research Findings*, Kaiser Family Found. (Jun. 01, 2017), https://www.kff.org/report-section/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings-table-2/ (highlighting several national and state level studies on the effects on cost-sharing); Ridley D.B., Axelsen K.J., *Impact of Medicaid preferred drug lists on therapeutic adherence*, 24 PHARMACOECONOMICS 65 (2006) http://www.ncbi.nlm.nih.gov/pubmed/17266389. *See also* Happe LE, Clark D, Holliday E, Young T*, A systematic literature review assessing the direction impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resources utilization*, J MANAG CARE SPEC PHARM; 207):67-84 (2014); Mullins CD, Shaya FT, Meng F, et al., *Persistence, switching, and discontinuation rates among patients receiving sertraline, paroxetine, and citalopram*, PHARMACOTHERAPY 25-660-7 (2005).

[281] *See Drug Resistance*, AIDS INFO (Jan. 28, 2019), https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/56/drug-resistance; Dana P. Goldman, et al., *The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made*, 33 HEALTH AFF., 430 (2014).

[282] 42 U.S.C. § 18022(a)(2).

[283] 42 U.S.C. § 18022(c); 42 U.S.C.§ 300gg–6(b); *see also* 29 C.F.R. § 2590.715-2711.

sharing protections to non-EHBs, and HHS has confirmed that plans can “continue to impose annual and lifetime dollar limits on benefits that do not fall within the definition of EHB.”[284] Thus, classifying a particular drug as covered but a non-EHB means that a patient will pay the full cost of the drug until the deductible is met, share costs with the plan (via copay or coinsurance) until the plan’s annual or lifetime cap is hit, and then the patient must pay out-of-pocket for all further costs for the drug.

Health plans have justified the classification of certain drugs as non-EHBs by arguing that if a plan covers the minimum required drugs, additional covered drugs are not EHBs.[285] Under HHS rules, the EHB category of prescription drugs includes, at a minimum, the greater of one drug in every United States Pharmacopeia category and class, or the same number of drugs in each category and class as the state’s EHB benchmark plan.[286]

HHS should make clear that while cost sharing can be an effective tool in reducing unnecessary medical care, it should not be used by issuers and other covered entities in a discriminatory manner.

B. Adverse tiering

In 2014, NHeLP and The AIDS Institute filed an HIV/AIDS discrimination complaint with the HHS Office for Civil Rights (OCR) against four Florida QHPs that placed all HIV medications, including generics, in the highest tier. By placing even generic drugs on the top tier, patients face high up-front costs in the form of expensive co-insurance and co-pays, as well as burdensome prior authorization requirements and quantity limits. These tactics are particularly hazardous for people living with HIV/AIDS. Gaps in anti-

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[284] *Frequently Asked Questions on Essential Health Benefits Bulletin* 4, CTRS. MEDICARE & MEDICAID SERVS. (Dec. 16, 2011), https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf.

[285] *2021 Albuquerque Public Schools Express Scripts Summary of Benefits*, EXPRESS SCRIPTS; Meghan Pasicznyk, *Copay Assistance Strategy Reduces Financial Burdens for Plans and Patients*, EVERNORTH (Oct. 7, 2021), https://www.express-scripts.com/corporate/articles/reducing-specialty-drug-costs.

[286] 45 C.F.R. § 156.122(a). Note the ACA explicitly states that the regulation should not be construed as limiting a plan if it wants to provide additional benefits. 42 U.S.C. § 18022(b)(5).

retroviral treatment can lead to the development of drug resistance and increased rates of new HIV infections.

In a study published in the New England Journal of Medicine in January 2015, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, researchers at the Harvard School of Public Health examined forty eight ACA health plans and found that a dozen of these plans placed medications used to treat HIV/AIDS in the highest cost-sharing tiers. This practice — known as “adverse tiering” —serves to discourage people with significant health needs from enrolling in the health plan.

The National Alliance on Mental Illness (NAMI) also identified adverse tiering for medications used in the treatment of mental illness in its April 2015 report *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care*.[287] NAMI commissioned a study for formularies for eighty four health plans to assess coverage of three classes of psychiatric medications: antipsychotics, antidepressants, and SSRIs/SNRIs used commonly to treat depression. The analysis found that many plans placed these medications on high cost sharing tiers or with restricted access.

Adverse tiering can have serious consequences by impeding access to potentially life-saving medications. Adverse tiering works for insurers by steering persons with significant health needs away from their plans. As a result, plans with more balanced tiering structures become more likely to enroll high-need patients. At this point, the more balanced health plan’s enrollment could become imbalanced, placing pressure on the health plan to change its coverage policies or raise premiums and/or deductibles. This can lead to a “race to the bottom” effect where the plans in the marketplace all start putting these medications in the highest-cost tiers. Meanwhile, people who most need coverage are left with few options.

HHS has since recognized that health plans in which most or all drugs used in the treatment for certain conditions are put into the highest cost sharing tier may violate the ACA’s non-discrimination requirements.[288]

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[287] NAMI, *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care*, at 4 (April 2015), https://www.nami.org/Support-Education/Publications-Reports/Public-Policy-Reports/A-Long-Road-Ahead/2015-ALongRoadAhead.

[288] See U.S. Dept. of Health and Human Srvs., *Notice of Benefit and Payment Parameters for 2016; Final Rule*, 80 Fed. Reg. 10750, 10822 (Feb. 27, 2015),

C. Narrow provider networks

Inadequate provider networks provide another opportunity for health insurers seeking to discriminate or otherwise discourage enrollment of persons with disabilities and other protected populations. For example, plans can limit or restrict access to certain types of healthcare professionals relied upon by persons with disabilities or limit the participation of safety-net and providers who serve in underserved areas.

Health plans may have limited or no access to certain providers, such as infectious disease specialists often accessed by persons living with HIV/AIDS, endocrinologists important for the treatment of persons with diabetes, or psychiatrists for persons with behavioral or mental health needs.

A study published in the October, 2015 Journal of the American Medical Association examined specialty provider access in 135 plans sold on HealthCare.gov across 34 states.[289] The specialists included those sought by individuals with common chronic medical conditions or those with high health needs, including in-network specialist physicians in obstetrics/gynecology, dermatology, cardiology, psychiatry, oncology, neurology, endocrinology, rheumatology, and pulmonology. Researchers found that 15% of those plans lacked in-network physicians for at least one specialty.

Health insurance companies routinely discriminate against individuals with mental illness—not only by failing to comply with the integration mandate, as noted below—but also via discriminatory benefit design. Insurers routinely make it more difficult for individuals to obtain mental health services than physical health services. For example, individuals are forced to go out of network much more often for outpatient mental health

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https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf. *See also* U.S. Dept. of Health and Human Srvs., *Notice of Benefit and Payment Parameters for 2023: Proposed Rule,* 87 Fed. Reg. 584, 667 – 668, (Jan. 5, 2022), https://www.govinfo.gov/content/pkg/FR-2022-01-05/pdf/2021-28317.pdf.

[289] Stephen C. Dorner, MSc, Douglas B. Jacobs, ScB, and Benjamin D. Sommers, MD, PhD, *Adequacy of Outpatient Specialty Care Access in Marketplace Plans Under the Affordable Care Act*, JAMA, (Oct. 27, 2015), https://jamanetwork.com/journals/jama/fullarticle/2466113.

services than for similar outpatient physical health providers.[290] This lack of access to in network providers leads much higher out-of-pocket costs for mental health care than physical health care.[291] A major factor contributing to the lack of access to in-network providers is the low reimbursement rate many insurers pay to mental health providers.[292] Insurers must not design plans and networks in a manner that serves to make it more difficult to access mental health care than physical health care, nor screen out individuals who have significant mental health care needs.

The American Academy of Actuaries Health Equity Work Group (HEWG) identified several features of narrow provider networks that can adversely affect communities experiencing poverty or communities with a concentrated number of people that belong to racial and ethnic minority groups. These include lower reimbursement rates, which can be especially harmful for providers serving serve under-resourced communities; and performance requirements related to cost or other outcome and quality measures which could prevent access and cause providers to avoid patients communities who experience high health needs.[293]

Narrow provider networks may also discriminate against other protected classes. Failure to provide access to child psychiatrists, for example, may constitute discrimination based upon age.

D. Unreasonable utilization management

Plan benefit design includes medical necessity criteria and other utilization management tools which may limit access to needed services and treatment. Data on treatment

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[290] National Alliance on Mental Illness, *The Doctor is Out: Continuing Disparities in Access to Mental and Physical Health Care* (2017), https://www.nami.org/Support-Education/Publications-Reports/Public-Policy-Reports/The-Doctor-is-Out/DoctorIsOut (hereinafter "NAMI").

[291] *Id.*

[292] Gov't Acct. Office, *Mental Health Care: Consumers with Coverage Face Access Challenges, Testimony Before the Committee on Finance, U.S. Senate* (March 30, 2022), https://www.gao.gov/assets/720/719824.pdf.

[293] American Academy of Actuaries, Health Equity Work Group, *Health Equity from an Actuarial Perspective: Provider Contracting and Network Development* (Sept. 2021), at 2, https://www.actuary.org/sites/default/files/2021-09/Health_Equity_Provider_Contract_Network_Develop_09.2021.pdf.

limitations is important to fully understand a plan's benefit coverage. However, information about treatment limitations can be difficult to find, even in a plan's Evidence of Coverage (EOC).

Arbitrary coverage denials can be built into an insurer's business plan. A recent study by the Kaiser Family Foundation found that plans sold through the ACA Marketplaces denied one in five claims; with some plans denying as much as 80% of in-network claims submitted.[294] That same study found that consumers rarely appeal denied claims. Of the more than 42 million denied in-network claims in 2020, marketplace enrollees appealed fewer than 61,000 – an appeal rate of about one-tenth of one percent.[295] Issuers upheld sixty-three percent of denials that were appealed.[296]

In its analysis of access to mental health benefits in ACA plans, NAMI found high rates of denials of authorization for mental health and substance use care by insurers.[297] Consumers reported that plans routinely denied care found to be reasonable, necessary and appropriate, based on evidence-based clinical standards of care.

In the NHeLP/TAI HIV discrimination complaint, the four Florida issuers required prior authorization for all HIV medications, imposed quantity limits, and restricted access to HIV treatments.

HHS should require health insurers and other covered entities to make information on utilization management, including quantitative and non-quantitative treatment limits, publicly available. HHS should collect and evaluate the data and identify any treatment limitations that might be discriminatory. Given the Secretary's obligations under the ACA, this data should be used to ensure that arbitrary and unreasonable limits that restrict access to needed care fall within § 1557 protections and enforcement actions.

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[294] Karen Pollitz, et al., Kaiser Family Found., *Claims Denials and Appeals in ACA Marketplace Plans in 2020* (Jul. 5, 2022), https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/. Note, there was no reason specified in 72% of claims analyzed.
[295] *Id*. at Figure 5.
[296] *Id.*
[297] See NAMI, *supra* note 290 at 4.

E. Formularies

Prescription drug formularies offer another opportunity for plans to discriminate through plan benefit design. In a 2013 rulemaking, HHS established a federal minimum standard for EHB prescription drug coverage – the greater of one drug per U.S. Pharmacopeia (USP) class and category, or the number in a state's benchmark plan.[298] That standard has proven inadequate to meet the needs of highly vulnerable patient populations that rely on prescription drugs.

Plans can meet the minimum EHB coverage standard, but not cover the most commonly prescribed medications used to treat certain conditions. For example, in 2014, HIV advocates raised concerns that QHPs failed to cover single tablet therapy for HIV.[299] Single tablet therapy is a combination of antiretroviral drugs in a single tablet and has become the standard of care in HIV treatment because it supports adherence and helps prevent drug resistance.[300] A subsequent study found "wide variation in coverage of EHBs across plans," and that EHB benchmark prescription drug coverage does not guarantee coverage of the most appropriate anti-retroviral therapy.[301]

Studies show there are significant gaps remain in accessing medications used to treat opioid use disorder (OUD). A 2019 study of state EHB benchmark plan coverage of OUD treatments and services found that approximately two-fifths of benchmark plans do not cover the opioid overdose reversal agent, naloxone, despite the fact that the

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[298] U.S. Dept. of Health & Human Srvs., *Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule*, 78 Fed. Reg. 12834 - 12872 (Feb. 25, 2013), https://www.govinfo.gov/content/pkg/FR-2013-02-25/pdf/2013-04084.pdf, *codified at* 45 C.F.R. § 156.122.

[299] *See, e.g.,* HIV Health Care Access Working Group, *Comments on CMS Notice of Payment and Benefit Parameters for 2016* (Dec. 22, 2014) at 2, https://www.regulations.gov/document?D=CMS-2014-0152-0144.

[300] U.S. Dept. Health & Human Srvs., *Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents* (last updated Aug. 16, 2021), https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf.

[301] Lauren Lipira, et al., *Evaluating the Impact of the Affordable Care Act on HIV Care, Outcomes, Prevention, and Disparities: A Critical Research Agenda*, 28 J. HEALTH CARE FOR POOR & UNDERSERVED 1256 (2017), https://muse.jhu.edu/article/677348/pdf.

current prescription drug standard implicitly requires coverage of this medication. Another study, from 2017, found that the vast majority of state benchmark plans are either silent or explicitly exclude methadone for opioid use disorder treatment.[302] HHS has recognized that failing to cover the most commonly used therapies or treatment protocols that serve as the standard of care for a medical condition is potentially discriminatory.[303]

F. Arbitrary coverage exclusions

People with developmental disabilities are routinely denied coverage for habilitative services, such as physical therapy, needed to gain skills or improve functioning while an identical service is provided to individuals who would require for a rehabilitative care to restore functioning. The essential health benefit category of rehabilitative and habilitative services and devices is a broad grouping of services and supports that benefit a wide variety of people with disabilities. The congressional intent of this provision was expressed by Rep. George Miller, Chairman of the House Committee on Education and Labor, a committee with primary jurisdiction over the House health reform bill, when he explained that the term rehabilitative and habilitative services:

> …includes items and services used to restore functional capacity, minimize limitations on physical and cognitive functions, and maintain or prevent deterioration of functioning. Such services also include training of individuals with mental and physical disabilities to enhance functional development.[304]

We have also seen a few states limit the availability of habilitative services and devices to people with autism. Limiting the coverage of habilitative services and devices to people with autism is discriminatory towards people with other disabilities and fails to ensure that coverage decisions focus on the individualized health care needs of each person. We contend that these types of blanket service exclusions should be

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[302] Stacey A. Tovino, *State Benchmark Plan Coverage of Opioid Use Disorder Treatment and Services: Trends and Limitations*, 70 S.C.L. REV. 763 (2019).

[303] See U.S. Dept. of Health and Human Srvs., *Notice of Benefit and Payment Parameters for 2016; Final Rule*, 80 Fed. Reg. 10750, 10822 (Feb. 27, 2015), https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.

[304] Congressional Record, H1882 (March 21, 2010).

considered “unlawful on its face” in the same manner that is proposed to apply to gender transition-related care, as excluding habilitation coverage systematically denies services for people with developmental disabilities and is prohibited discrimination on the basis of disability.

Additionally, EHB benchmark packages approved by the Secretary continue to include hard limits on the coverage of habilitative and rehabilitative services and devices, especially in a total number of visits allowed. These limits are a de-facto annual monetary cap on coverage – violating ACA § 1302 and § 1557 - because they discriminate against people with more significant disabilities who are the only beneficiaries who need this level of therapy. Limitations on the number of covered visits without regard for medical necessity, best medical practices, or the extent of therapy prescribed to the individual discriminates against people with more significant disabilities who need this extensive habilitation or rehabilitation in order to gain, regain, or maintain functioning.

G. Clinical guidelines framework for discriminatory benefit design

The Notice of Benefit and Payment Parameters Rule for 2023 clarified that “a non-discriminatory benefit design that provides EHB is one that is clinically-based.”[305] In our comments, we expressed general support for evaluating plan benefit design with consideration of clinical guidelines and the standard of care, while also recognizing that clinical guidelines may embed racial bias.[306]

We reiterate that general support, and urge HHS to harmonize the § 1557 regulation for nondiscrimination in benefit design, with its EHB counterpart at 45 C.F.R.

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[305] U.S. Dept. of Health and Human Srvs., *Notice of Benefit and Payment Parameters for 2023*, 87 Fed. Reg. 27208-27393 (May 6, 2022), https://www.govinfo.gov/content/pkg/FR-2022-05-06/pdf/2022-09438.pdf, *codified* at 45 C.F.R. § 156.125(a).

[306] *See* Letter from Elizabeth G. Taylor, Nat’l Health Law Program, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services and Dr. Ellen Montz, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight, *Re: RIN 0938-AU65; CMS-9911-P Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023* (Jan. 27, 2022), https://healthlaw.org/resource/nhelp-comments-on-2023-notice-of-benefit-and-payment-parameters-proposed-rule/.

§ 156.125(a).[307] However, we ask that HHS consider our concerns regarding bias in peer-reviewed journals and data, and the connection of those issues to clinical guidelines to protect against the use of improper use of clinical guidelines as a shield for discrimination.

Requiring plan benefit design features to be clinically-based represents a promising starting point for evaluating plans, but it may not capture the full range of discriminatory practices and could unintentionally reinforce bias. Relying exclusively on clinical guidelines and journal articles could unduly limit HHS's plan analysis for discriminatory design. Moreover, an insurer could cite a single peer-reviewed article to justify a discriminatory plan feature.[308]

We also note that peer-reviewed journals can perpetuate health disparities. Recent research has identified that peer-reviewed medical journals can have a significant racial bias.[309] This compounds acknowledged bias in clinical trials, data sets, and how clinician bias may affect data.[310] Since most health care guidelines are based on this

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[307] We recognize that some plans subject to EHB standards, including 45 C.F.R. § 156.125(a), may not be subject to § 1557, and plans subject to § 1557 are not necessarily subject to EHB requirements.

[308] *See, e.g,* Julie A Schmittdiel et al., *The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients,* Am. J. Managed Care (Nov. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278640/ (showing that that mail order pharmacy can help some patients with medication adherence).

[309] Rhea Boyd et al., *The World's Leading Medical Journals Don't Write About Racism. That's a Problem,* TIME (Apr. 21, 2021) (finding that the top four medical journals in the world almost never publish scientific articles that name racism as a driver of poor health outcomes and less than 1% of the 200,000 articles published over the past 30 years included "racism" anywhere in the text; of the few articles that did, 90% were predominately opinion pieces); Usha Lee McFarling, *When a Cardiologist Flagged the Lack of Diversity at Premier Medical Journals, the Silence was Telling,* STAT (Apr. 12, 2021), https://www.statnews.com/2021/04/12/lack-of-diversity-at-premier-medical-journals-jama-nejm/ (discussing the impact on research from the lack of diversity at premier medical journals).

[310] *E.g.,* Donna Christensen et al., *Medical Algorithms Are Failing Communities of Color,* HEALTH AFF. FOREFRONT (Sept. 9, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210903.976632/full/ (citing the lack of diversity in medical data, including clinical trials and the failure of data based tools to reflect the population they are being used on); Michael Sun et al., *Negative Patient Descriptors:*

information, bias often gets compounded again, not to mention the impact of financial considerations that often come into play in coverage guidelines.[311]

Health care has a long history of institutional bias that includes explicit and implicit bias, and has centered the white, heteronormative experience.[312] A 2020 study published in the New England Journal of Medicine identified thirteen clinical diagnostic tools that use race adjustment.[313]

Documenting Racial Bias in the Electronic Health Record, HEALTH AFF. (Jan.19, 2022), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01423 (finding Black patients had 2.54 times the odds of having at least one negative descriptor in their EHR); Ziad Obermeyer, *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCIENCE 447 (Oct. 25, 2019), https://science.sciencemag.org/content/366/6464/447 (identifying racial bias in health care allocation algorithm because it was based in spending rather than need); *see generally* Melissa D. McCradden et al., *Ethical Limitations of Algorithmic Fairness in Health Care Machine Learning*, 2 THE LANCET E222 (May 2020); Ibram X. Kendi, *There is No Such Thing as Race in Health-care* Algorithms, 1:8 THE LANCET E375 (Dec. 2019), https://www.thelancet.com/journals/landig/article/PIIS2589-7500(19)30201-8/fulltext; Rachel R. Hardeman, Eduardo M. Medina & Katy Kozhimannil, *Structural Racism and Supporting Black Lives—The Role of Health Professionals*, 375 NEW ENG. J. MED. 2113 (Dec. 1, 2016) (summarizing sources of bias in health care).

[311] *See, e.g., Wit v. United Behavioral Healthcare*, 14-cv-2346-JCS, 2019 WL 1033730 (N.D. Cal. July, 27, 2020) (finding parity compliance issues with utilization management tools that used criteria that did not align with clinically accepted criteria and was unduly influenced by fiscal rationales).

[312] See Kendi, *supra* note 310*. See also*, Rachel R. Hardeman, Eduardo M. Medina & Katy Kozhimannil, *Structural Racism and Supporting Black Lives—The Role of Health Professionals*, 375 NEW ENG. J. MED. 2113 (Dec. 1, 2016) (summarizing sources of bias in health care); Michael Sun et al., *Negative Patient Descriptors: Documenting Racial Bias in the Electronic Health Record,* 41 HEALTH AFF. 1 (Feb. 2022), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01423.

[313] Darshali A Vyas, Leo G Eisenstein, David S Jones, *Hidden in Plain Sight: Reconsidering the Use of Race Correction in Clinical Algorithms,* NEW ENGLAND JOURNAL OF MEDICINE, Volume 383, Issue 9, Page 874-882 (Aug. 2020). These diagnostic tools include: American Heart Association Get with the Guidelines-Heart Failure; Society of Thoracic Surgeons Short-Term Risk Calculator; eGFR (updated to no longer include race adjustment); Kidney Donor Risk Index (KDRI); Vaginal Birth after Cesarean Risk Calculator (updated to no longer include race adjustment); STONE Score; UTI Calculator (updated to no longer include race adjustment); Rectal Cancer Survival Calculator; National Cancer Institute Breast Cancer Risk Assessment

Data collection, research, determinations regarding cause and outcomes, and analyses can be informed by institutional bias within the system.[314] This does not mean that peer-reviewed journals, clinical guidelines, should not be relied upon for determining medical necessity or the appropriateness of care, but we are concerned that relying on them exclusively opens the door for plans to use this type of research as a shield and escape valid claims of discriminatory benefit design.[315] In addition, there is often a lack of transparency about the data and underlying assumptions of studies and tools that makes it difficult to call into question their validity, especially when many are protected as trade secrets or intellectual property.

Because of the acknowledged biases, HHS should use a multi-prong approach in evaluating plans health plan coverage and programmatic decisions, protect against the creation of safe harbors for benefit design, and improve transparency. Notwithstanding its limitations, we recommend that HHS specify in § 1557 regulations that a non-discriminatory benefit design is one that is clinically-based.

Insurers and other covered entities should be required to provide medical necessity standards and other benefit design features, and demonstrate how they align with clinical, evidence-based criteria or guidelines. We urge HHS to more fully incorporate

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Tool; Breast Cancer Surveillance Consortium Risk Calculator; Osteoporosis Risk Score; Fracture Risk Assessment Tool; and Pulmonary-function tests.

[314] *See, e.g.,* Hannah E Knight et al., *Challenging Racism in the Use of Health Data*, 3:3 THE LANCET E144 (Feb. 3, 2021) (explaining how structural inequalities, biases, and racism in society are easily encoded in datasets and application of data science and how it can reinforce existing injustices and inequalities).

[315] When HUD proposed language that would have allowed a degree of deference to algorithmic decision making in disparate act claims, there was significant push back because of the institutional racism in housing, the prevalence of proxy discrimination, and other issues with relying on an algorithm in that field. Health care has similar deeply engrained institutional biases. *See, e.g.,* Elizabeth Edwards, David Machledt & Hannah Eichner, Nat'l Health Law Program, *Comments on HUD Disparate Impact Rule Changes and the Use of Algorithms* (Oct. 18, 2019), https://healthlaw.org/resource/comments-on-hud-disparate-impact-rule-changes-and-the-use-of-algorithms/; Deborah Archer, AI Now Institute and Ctr. on Race, Inequality & the Law, *Comments on HUD's Implementation of the Fair Housing Act's Disparate Impact Standard* (Oct. 18, 2019), https://www.regulations.gov/comment/HUD-2019-0067-2746.

the lessons learned from the Mental Health Parity rules and guidance cited.[316] As evidenced by the evolving history of Mental Health Parity investigations, HHS should be very clear that not only standards and guidelines, but also the process measures, include evidence of how they align with generally-accepted standard of care, evidentiary standards, and other factors used to determine coverage.[317] This should include, similar to what is required under Parity, the methods and analysis used to develop the standards, any evidence and document to establish non-discrimination as written, and *in operation*. Importantly, HHS should be clear that covered entities cannot fail to disclose criteria based on claims of proprietary information.[318]

As the history of parity requirements, enforcement, noncompliance, and additional standards added to try to rein in the discriminatory activities of insurers shows, what can and should be examined in response to allegations of discriminatory benefit design or coverage decisions needs to be sufficiently detailed and in depth. All necessary information needs to be disclosed to those impacted and enforcement entities.[319] As discussed in § 92.201 regarding clinical algorithms, a mere examination of the standard does not necessarily reveal the bias – a facially neutral standard may have disparate impact, may be based in biased data or analyses, or included flawed analysis or programming. HHS should learn from the lessons of Parity enforcement about the depth of information needed and how plans have evaded compliance to create clear requirements early on about what they will be required to show in an investigation and what should be available from disclosure requests

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[316] 87 Fed. Reg. 47874 n. 472

[317] For a discussion of the history of mental health parity legislation, requirements of plans, how plans employed techniques that denied services in new ways, and subsequent legislation and enforcement activities, including supporting sources, *see, e.g.,* Amicus Brief of Nat'l Health L. Program & The Kennedy Forum in *E.W. v. Health Net*, *available at* *https://healthlaw.org/resource/amicus-brief-of-nhelp-and-the-kennedy-forum-in-e-w-v health/?fbclid=IwAR3sBc20UO2ZqOhO1GbjHGuJJeboMAQ1T1lmH6K-IynOiIasEBoC5muxFwM.*

[318] U.S. Dep't of Labor, *Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA)* 21 (2018), https://perma.cc/Z86U-JH9E.

[319] *See, e.g.,* Amicus Brief of Nat'l Health L. Program & The Kennedy Forum, *supra* note 317; *N.R. v. Raytheon,* 24 F.4th 740 (1st Cir. 2022) (discussing the importance of disclosure of plan documents).

We also appreciate the 2022 Proposed Rule specifically mentions exclusions, limitations, and cost sharing as they relate to gender affirming care.[320] However, issuers and other covered entities can deploy these and other discriminatory benefit design features in other contexts, including unlawfully targeting persons with disabilities, chronic conditions, and others with significant health needs. While HHS acknowledges these features of benefit design in the preamble, we believe HHS should include a non-exhaustive list in the regulatory text.[321]

Individuals' experiences continue to include discrimination in benefit design, leading further support to the Proposed Rule. These experiences include:

- In Washington, an individual with hearing loss that requires treatment other than cochlear implants was denied coverage of her hearing aids and outpatient visits to an audiologist due to her insurer's blanket exclusion of programs or treatments for hearing loss other than cochlear implants.[322]

- In 2014, the National Health Law Program filed an administrative complaint with HHS OCR based on an analysis of coverage of HIV/AIDS medication in prescription drug formularies for silver-level plans sold in Florida. Four issuers placed every commonly prescribed HIV/AIDS medication, including generic drugs, into the highest cost sharing tiers in their formularies, a practice known as "adverse tiering." A subsequent analysis conducted by PhRMA found other plans that subjected multiple sclerosis and cancer to the same type of discriminatory cost sharing.[323]

Accordingly, we also recommend HHS include a non-exhaustive list of potentially discriminatory plan benefit design features in the regulatory text.

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[320] Proposed § 92.207(b)(3)-(5).

[321] 87 Fed. Reg. 47869.

[322] Br. of the National Health Law Program and Northwest Health Law Advocates as Amicus Curiae at 27-28, *Schmitt v. Kaiser Found. Health Plan Wash*., No. 18-35846 (9th Cir. Jan. 29, 2019) (available from NHeLP). *See also* Complaint at 3,5 ¶¶ 6, 13, *Schmitt v. Kaiser Found. Health Plan Wash*., No. 2:17-cv-1611 (W.D. Wash. Oct. 30, 2017) (available from NHeLP).

[323] Br. of the National Health Law Program and Northwest Health Law Advocates as Amicus Curiae at 21-22, *Schmitt v. Kaiser Found. Health Plan Wash*., No. 18-35846 (9th Cir. Jan. 29, 2019) (available from NHeLP).

RECOMMENDATION: Amend § 92.207(b)(2) as follows:

(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***. A non-discriminatory benefit design is one that is clinically-based. Examples of benefit design features may include:***

- ***(i) coverage exclusions;***
- ***(ii) limitations of benefits;***
- ***(iii) prescription drug formularies;***
- ***(iv) cost sharing (including copays, coinsurance, and deductibles);***
- ***(v) utilization management techniques (such as step therapy and prior authorization);***
- ***(vi) medical management standards (including medical necessity standards);***
- ***(vii) provider network design; and***
- ***(viii) reimbursement rates to providers and standards for provider admission to participate in a network;***

H. Sex Discrimination

U.S. health insurance and other health-related coverage have long discriminated against applicants and enrollees on the basis of sex and intersecting identities. We agree with HHS's judgment that the statutory text of § 1557 is clear: Congress intended that the law's protections against discrimination on the basis of race, color, national origin, sex, age, and disability apply to these entities and address these issues. Thus, we strongly support HHS's restoration of and improvements to § 92.207. We urge HHS to strengthen its approach through our specific recommendations below.

i. Proposed § 92.207(b)(3)-(5)

We strongly support HHS's enumeration of specific forms of discrimination under § 92.207(b), including specific clarifications to protect LGBTQI+ people. We offer analysis and recommendations to strengthen HHS's proposed approach further below. However, as with Proposed § 92.206(b), HHS must strengthen its proposed text for §§

92.207(b)(4) and (5) to clarify protections against sex discrimination related to pregnancy or related conditions in health insurance and health-related coverage. For example, this includes coverage and claim exclusions and limitations for termination of pregnancy, assisted reproduction (including fertility care), contraception, pregnancy-related services, and other services.

HHS must also insert an additional provision to clarify that denying or limiting coverage of, or coverage of a claim for, health services because they may prevent, cause complications to, or end fertility or pregnancies is prohibited. As discussed in our comments on § 92.206, in the wake of *Dobbs*, covered entities are increasingly denying or limiting access to medications and treatments that can prevent, cause complications to, or end pregnancies. While reporting often centers on denials by pharmacies, *Dobbs* is also having a chilling effect on coverage. For example, even in states where abortion remains legal, such as Maryland, some health insurers have informed enrollees who take methotrexate for autoimmune or other health conditions that they will no longer cover the drug.[324] As such, HHS must ensure that health insurance and health-related plans do not begin to deny or limit coverage for services that could prevent, cause complications to, or end fertility or pregnancies, including medications or treatments for disabilities or emergency medical conditions as defined in EMTALA. Explicitly including this form of discrimination in § 92.207(b) is critical to ensuring effective implementation of §§ 92.101 and 92.207. We recommend specific language to this effect at the end of our comments on Proposed § 92.207(b).

ii. Proposed § 92.207(b)(3)

As we discussed in our comments on Proposed § 92.206(b), we strongly support HHS's proposed clarification in § 92.207(b)(3) that sex discrimination includes discrimination on the basis of sex at birth, recorded gender, or gender identity. This change from the 2020 Final Rule is necessary to eradicate direct discrimination in health insurance against Transgender, Non-Binary Gender Diverse, and Intersex individuals. Despite § 1557 protections, insurers still bar individuals from receiving medically necessary, gender-affirming care because of the individual's recorded or perceived sex or gender

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[324] Jen Christensen, *Women with Chronic Conditions Struggle To Find Medications After Abortion Laws Limit Access*, CNN, Jul. 22, 2022, https://www.cnn.com/2022/07/22/health/abortion-law-medications-methotrexate/index.html.

identity.[325] Recently released 2022 survey data from the Center for American Progress and the University of Chicago found that over one in four Transgender or Non-Binary people experienced a denial of insurance coverage for gender-affirming care in the past year.[326] The same survey found that nearly half of Transgender and Non-Binary People of Color experienced an insurance denial for gender-affirming care in the past year.[327] Thus, strong regulations are needed to clarify the scope of prohibited actions and strong enforcement is needed to address violations.

HHS's proposed change from the 2020 Final Rule would also help eliminate barriers to care and protect medically necessary care for all individuals, no matter their sex or gender. Insurers have historically limited certain types of care to the recorded sex or gender of the individual (so called "sex specific" care).[328] Under this model, for example, only individuals with the sex designation "F" may receive coverage for cervical cancer screening. Insurers would deny coverage for an Intersex individual's oophorectomy because that individual's sex designation is "M."

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[325] *See, e.g.*, Keren Landman, *Fresh Challenges To State Exclusions on Transgender Health Coverage*, NAT'L PUB. RADIO, Mar. 12, 2019, https://www.npr.org/sections/health-shots/2019/03/12/701510605/fresh-challenges-to-state-exclusions-on-transgender-health-coverage ("Although federal law prohibits health insurance plans from discriminating against transgender individuals, the plan adopted by Houston County specifically excludes trans-related health care from coverage."); *see also Kadel v. Folwell*, — F.Supp.3d — (M.D.N.C. Mar. 11, 2020) (challenging exclusion of transgender health care from state employees' health plan); *Flack v. Wisconsin Department of Health Services*, 395 F.Supp.3d 1001 (W.D. Wis. 2019) (challenging exclusion of transition-related care from Medicaid coverage in violation of § 1557). Both courts ruled that such exclusions of transition-related care constituted sex discrimination against transgender individuals.

[326] Caroline Medina & Lindsay Mahowald, Ctr. for Am. Progress, *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities* (2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/.

[327] *Id*.

[328] *See* Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities*, Ctr. for Am. Progress, Aug. 18, 2021, https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/.

Developments in medicine have acknowledged that care is more appropriately linked to an organ inventory or current assessment of an individual's sex traits.[329] For example, a Transgender man with a cervix and a family history of cervical cancer needs medically necessary coverage of cervical cancer screening, but a cisgender woman who has had her cervix removed may not. An individual may be cisgender or Transgender, Intersex or Endosex, and for various reasons need access to "sex-specific" care such as prostate cancer screening or emergency contraception. Access is needed regardless of the individual's recorded or perceived sex or gender identity.

iii. Proposed § 92.207(b)(4)

a. Gender-Affirming Care

This provision importantly clarifies that § 1557's prohibition on sex discrimination includes categorical exclusions and limitations on coverage of gender-affirming care. We strongly believe that this clarity is needed to counter specific and ongoing sex discrimination by plans against transgender and gender diverse individuals.

Research has long demonstrated egregious discrimination in insurance coverage for Transgender, Non-Binary, and Gender Diverse individuals.[330] Even with access to health insurance, disparities in coverage persisted due to coverage exclusions, limitations, and restrictions that specifically target transition-related and gender-affirming care.[331] In addition to the coverage denials discussed above, about one in four

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[329] See State Health Access Data Assistance Ctr. (SHADAC), *Collection of Sexual Orientation and Gender Identity (SOGI) Data: Considerations for Medicaid and Spotlight on Oregon* 8 (2021), https://www.shvs.org/wp-content/uploads/2021/10/SOGI-Data-Collection-in-Medicaid_SHVS-Issue-Brief_Revised.pdf; Madeline B. Deutsch et al., *Electronic medical records and the transgender patient: recommendations from the World Professional Association for Transgender Health EMR Working Group*, 20 J. AM. MED. INFORM. ASSOC. 700 (2013).

[330] Am. Med. Assoc. & GLMA, *Issue Brief: Health insurance coverage for gender-affirming care of transgender patients* (2019), https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf.

[331] See Keren Landman, *Fresh Challenges To State Exclusions On Transgender Health Coverage*, NAT'L PUB. RADIO, Mar. 12, 2019, https://www.npr.org/sections/health-shots/2019/03/12/701510605/fresh-challenges-to-state-exclusions-on-transgender-health-coverage; Nat'l Academies of Sci., Engineering, & Med., *Understanding the Well-Being of*

Transgender or Non-Binary individuals experienced coverage limitations and one in three experienced burdensome cost-sharing requirements in the past year.[332] These disparities only multiply for Black, Indigenous, and other Transgender People of Color, Transgender People with disabilities, and Transgender people who are members of multiple underserved communities.[333]

The language in this proposed provision directly addresses these specific discriminatory actions that impede access to medically necessary health care. The continued use of exclusions, limitations, and restrictions by insurers demonstrates that the 2016 and 2020 Final Rules did not adequately address these issues; specific language is needed to counter denials that still take place. We strongly support language in the rule that addresses direct coverage exclusions (*i.e.*, no coverage for gender-affirming care in the policy) and indirect coverage exclusions (*e.g.*, only some gender-affirming care is covered, the insurer's network does not include providers of gender-affirming care and the insurer refuses to cover out-of-network providers) or limitations (*e.g.*, cost-sharing requirements make procedures unaffordable for most, or overly burdensome medical necessity criteria render care inaccessible Such exclusions are not rooted in well-established standards of care. On the contrary, exclusions and limitations of such care harm Transgender and Gender Diverse individuals and are counter to the medical recommendations put forth by the World Professional Association of Transgender Health, American Medical Association,[334] American Psychiatric Association,[335]

LGBTQI+ Populations (2020), https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf.

[332] Medina & Mahowald, *supra* note 127.

[333] *Id.*

[334] *See* World Professional Ass'n Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, 23 INTERNAT'L J. TRANSGENDER HEALTH S1 (8th Ed. 2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644; World Professional Ass'n Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* (7th ed. 2011), https://www.wpath.org/publications/soc.

[335] *See* Eric Yarbrough et al., Am. Psych. Ass'n, *A Guide for Working With Transgender and Gender Nonconforming Patients* (2017), https://www.psychiatry.org/psychiatrists/diversity/education/transgender-and-gender-nonconforming-patients; *see also* Am. Psych. Ass'n, *Position Statement on Treatment of Transgender (Trans) and*

American Psychological Association,[336] American Academy of Pediatrics,[337] and every other major medical association.[338].

Vital to the success of § 1557 implementation, this provision must address direct exclusions as well as indirect, functional exclusions. As discussed above, without specific language prohibiting categorical exclusions, insurers will continue to engage in discriminatory practices.[339] Functional exclusions operate perniciously in much the same way as direct exclusions to produce the same result: a barrier to medically necessary care to the detriment of a historically marginalized population. For example, a plan that covers gender affirming care but does not include providers in its network that provide this care violates this rule because it effectively prevents enrollees from accessing that coverage.[340] Likewise, a plan that imposes prior authorization

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Gender Diverse Youth (2020), https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

[336] *See* Jennifer Kelly, Am. Psychological Ass'n, *Politicians Should Follow the Science on Gender-Affirmation Treatments*, THE HILL, Apr. 29, 2021, https://thehill.com/opinion/civil-rights/550937-politicians-should-follow-the-science-on-gender-affirmation-treatments; *see also* Am. Psychological Ass'n*, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 AM. PSYCHOLOGIST 832 (2015).

[337] *See* Jason Rafferty et al., Am. Acad. Pediatrics, *Policy Statement: Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 PEDIATRICS 1 (2018).

[338] *See* Transgender Legal Defense & Educ. Fund, Medical Organization Statements, https://transhealthproject.org/resources/medical-organization-statements (collecting statements of various medical associations) (last visited Sep. 28, 2022).

[339] *See* Nat'l Academies of Sci., Engineering, & Med., *supra* note 120; Medina & Mahowald, *supra* note 127.

[340] *See* Matthew Bakko and Shanna Kattari, *Transgender-Related Insurance Denials as Barriers to Transgender Healthcare: Differences in Experience by Insurance Type*, 35 J. GEN. INTERN. MED. 1693 (2020) (finding that one in five individuals with private insurance - and one in three individuals with Medicare or Medicaid - could not find an in-network provider for gender affirming surgery despite the service being covered). We acknowledge that due to gaps in medical education, structural stigma, and other factors may limit affirming or competent providers in certain areas. *See* Samuel B. Dubin et al., *Transgender Health Care: Improving Medical Students' and Residents' Training and Awareness* 9 ADV. MED. EDUC. PRACT. 377 (2018); Nat'l Academies of Sci., Engineering, & Med., *supra* note 120. However, under § 1557 plans have

requirements on transition-related surgery but does not impose the same requirements for other conditions discriminates in violation of this rule. Insurers that classify certain gender affirming or transition-related services as cosmetic or experimental contravene the medical determinations of experts as well as violate the civil rights of Transgender and Gender Diverse individuals.[341]

We believe that HHS can strengthen the language of this subsection by inserting "any or" before "all." We agree that it is important to clarify that excluding or placing limitations or restrictions on all gender transition or other gender-affirming care is discriminatory. As drafted, however, this provision could be misconstrued to only apply if health insurance or health-related coverage excludes "all" health services related to gender transition or other gender-affirming care, whereas we believe the true intent is to also proscribe exclusions of "any" such services. We recommend a specific amendment to clarify this and further strengthen this provision below.

b. Pregnancy or Related Conditions, Including Termination of Pregnancy

In addition to the issues related to medically necessary care Transgender, Non-Binary, and Gender Diverse individuals, this provision should also address pregnancy and related conditions, including termination of pregnancy. For example, some health insurance issuers refuse to cover certain types of assisted reproduction, such as in vitro fertilization (IVF), for these populations.[342] Private and public health plans often discriminate based on relationship status and sexual orientation with policies that require single people or those in queer relationships to pay out of pocket for a

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an affirmative obligation to counsel members on options to ensure that the full range of gender affirming care is available, including by arranging for transportation and travel, and for enrollees to see out-of-network providers, when necessary.

[341] *See* World Prof. Assoc. For Transgender People, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People: 7th Version* 8-10 (2012); State of Connecticut, Comm'n on Hum. Rights & Opportunities, *Declaratory Ruling On Petition Regarding Health Insurers' Categorization Of Certain Gender-Confirming Procedures As Cosmetic* 4 (Apr. 17, 2020), https://www.glad.org/wp-content/uploads/2020/04/Dec-Rule_04152020.pdf.

[342] Gabriela Weigel et al., Kaiser Family Found., Coverage and Use of Fertility Services in the U.S. (2020), https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s.

predetermined number of failed intrauterine insemination cycles before providing them coverage when cisgender male-female couples do not have to meet the same standard. The high cost and lack of coverage for assisted reproduction, including IVF, are large barriers for people who experience multiple and intersecting forms of discrimination.[343]

Given how pervasive this sex discrimination is in health coverage, HHS should amend Proposed § 92.207(b)(4) to include reproductive and sexual health services, such as assisted reproduction. This should include services for which covered entities have historically implemented discriminatory categorical coverage exclusion or limitations. Because discrimination related to pregnancy or related conditions can also target broader health services, we ask that this provision not only list reproductive and sexual health, but also include services writ large (*see* Recommendations below).

iv. Proposed § 92.207(b)(5)

We support inclusion of this provision in the 2022 Final Rule. This provision is necessary to capture additional discriminatory tactics that health insurers may employ to restrict or bar access to critical services for Transgender, Non-Binary, Gender Diverse, and Intersex individuals.

This provision protects Transgender, Non-Binary, Gender Diverse, and Intersex individuals from several types of sex discrimination that prevent access to gender affirming care. First, it addresses sex discrimination that Transgender, Gender Diverse, and Intersex individuals may face as a result of direct discrimination. For example, this provision prohibits denials, limitations, exclusions, or restrictions on coverage for a Transgender woman's orchiectomy if they are due to the fact that her sex designation is "F," or if they are based on the fact that she is Transgender.

Recent examples of discrimination also include an insurer imposing additional cost-sharing on a gender-affirming medical procedure simply because it is gender-affirming, or requiring prior authorization for electrolysis related to gender affirming surgery.[344] Gender-affirming surgeries are not cosmetic, but are accepted medical standards of

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[343] *See generally* McCaman Taylor et al., *supra* note 229.

[344] *See* Helen Santoro, *Medical Coding Creates Barriers to Care for Transgender Patients*, KAISER HEALTH NEWS, Sept. 13, 2022, https://khn.org/news/article/medical-coding-creates-barriers-to-care-for-transgender-patients/.

care for Transgender and Gender Diverse individuals or those individuals with a diagnosis of gender dysphoria.[345] For example, Transgender and Gender Diverse individuals must have access to hair removal services in order to safely proceed with certain gender-affirming procedures, otherwise providers will not perform the procedure. Unfortunately, it is common for insurance companies to issue blanket exclusions on hair removal services as a basis for denying such services to Transgender and Gender-Diverse individuals. This results in frustrating and exhausting barriers to care.[346] As above, this change from the 2020 Final Rule remains necessary to combat specific, persistent forms of discrimination that are still exceedingly common.

Second, this provision addresses sex discrimination on the basis of a sex stereotype. For example, it prohibits an insurer from denying a Non-Binary person a mammogram because the individual seeking coverage speaks with a low voice on the phone. Discrimination in the form of sex stereotyping is prohibited when an insurer makes a determination based solely on its stereotyped expectations of an individual's recorded or perceived sex, rather than on what is determined medically necessary.

Per our recommendations regarding Proposed § 92.207(b)(4), we urge HHS to amend Proposed § 92.207(b)(5) to include forms of reproductive and sexual health care that covered entities have historically implemented discriminatory categorical coverage exclusion or limitations on, otherwise denied or limited, denied or limited claims for, or imposed additional cost-sharing such as assisted reproduction. Moreover, this provision should also clarify that § 1557 prohibits sex discrimination related to pregnancy or related conditions no matter the health service involved. We recommend specific amendments below.

Lastly, we believe this provision will be clearer if HHS strikes "if such denial, limitation, or restriction results in sex discrimination." The purpose of this provision is to clarify that denying, limiting, or restricting coverage for the listed services is prohibited discrimination under § 1557. Thus, we think the text we recommend striking is unnecessary. As well, we are concerned that this language may be limiting, as

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[345] Nat'l Academies of Sci., Engineering, & Med., *supra* note 120.

[346] *See* Helen Santoro, *supra* note 344.

RECOMMENDATION: We urge you to amend proposed § 92.207(b) as follows:

> (4) Have or implement a categorical coverage exclusion or limitation for all services related to gender transition or other gender-affirming care**, *termination of pregnancy, contraception, assisted reproduction including fertility care, miscarriage management, pregnancy-related services, other reproductive and sexual health services, or any health services***;
>
> (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, ***termination of pregnancy, contraception, assisted reproduction including fertility care, miscarriage management, pregnancy loss, pregnancy-related services, other reproductive and sexual health services, or any health services*** **~~if such denial, limitation, or restriction results in discrimination on the basis of sex~~; or**
>
> . . .
>
> ***(7) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations on coverage for health services because they may prevent, cause complications to, or end fertility or pregnancies.***

Following this rulemaking, HHS should also issue guidance to covered entities who issue health insurance or health-related coverage with specific hypotheticals of LGBTQI+ discrimination that may be prohibited under § 1557. This guidance should be akin to HHS's recent guidance to pharmacies.[347] In particular, Non-Binary and Intersex individuals, Transgender, and Gender Diverse individuals, may experience particular challenges, as their sex traits do not align solely with binary male or female sex characteristics. We believe that *Bostock* as well as § 1557 prohibit these kinds of coverage denials. In addition, it would be valuable for this guidance to offer examples of circumstances that operate as a functional exclusions of coverage as well as explicit exclusions or limitations. We believe that offering covered entities as well as the public

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[347] *See* HHS Guidance to Pharmacies, *supra* note 230.

examples of how prohibited sex discrimination in coverage against LGBTQI+ people can manifest is important to support effective § 1557 implementation.

I. Requiring Services in the Most Integrated Setting Appropriate to the Needs of Individuals with Disabilities

NHeLP strongly supports the inclusion of integration mandate language in the provisions regarding nondiscrimination in health coverage at Proposed § 92.207(b)(6). Section 1557 explicitly references § 504, which has regulatory requirements to provide services and programs in the most integrated setting appropriate to the needs of individuals with disabilities and has consistently been interpreted as requiring those receiving federal financial assistance to not segregate individuals with disabilities from their communities.[348] Importantly, § 504 also prohibits covered entities from utilizing criteria or methods of administration that "have the purpose of or effect defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity" or otherwise discriminates against people with disabilities.[349] Therefore, covered entities under § 1557 are prohibited from providing health program and

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[348] 45 C.F.R § 84.4(b)(2) ("aids, benefits, and services . . . [must afford equal opportunity] . . . in the most integrated setting appropriate to the person's needs."); *Olmstead v. L.C. ex rel. Zimring,* 527 U.S. 581 (1999); *see, e.g.*, *Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013) (both Section 504 and the ADA contain the same integration requirements and the claims may be considered together); *Am. Council of the Blind v. Paulson*, 525 F.3d 1256, 1266 (D.C. Cir. 2008); *Henrietta D. v. Bloomberg,* 331 F. 3d 261, 272 (2d Cir. 2003); *see also Townsend v. Quasim*, 328 F.3d 511, 517 (9th Cir. 2003) (where the issue is the location of services provided ─institution versus community─rather than whether services should be provided, *Olmstead* controls). Although the Court in *Olmstead* noted that § 504 does not contain the same express recognition that isolation or segregation of persons with disabilities is form of segregation, the regulations make such a recognition and case law enforcing the community integration mandate have consistently found violations of § 504 due to segregation of people with disabilities and not providing services in the most integrated setting appropriate to their needs. *See, e.g., Day v. D.C.,* 894 F. Supp. 2d 1, 4 (D.D.C. 2012) (noting the lack of express recognition but relying on the regulations); *Steimel v. Wernert,* 823 F.3d 902, 911 (7th Cir. 2016) (finding integration mandate violations because the Defendant's service system design, planning, funding choices, and service implementation promoted or relied on segregation of people with disabilities); *Waskul v. Washtenaw Cnty. Cmty. Mental Health,* 979 F.3d 426, 462 (6th Cir. 2020) (policies limiting plaintiffs' access to the community and activities violated the integration mandated).

[349] 45 C.F.R. § 84.4(b)(4).

services in settings that are more segregated than are appropriate to the needs of people with disabilities, and from employing coverage policies, benefit design, coverage decisions, and other criteria and methods of administration that will do the same.[350] Including integration mandate language in the rule will therefore provide greater clarity. As one example of the need for integrated settings, in January 2016, a woman with quadriplegia enrolled in Indiana's Medicaid program was admitted to the hospital for pneumonia, which doctors treated and resolved within a week. She met the criteria for discharge, but remained hospitalized for over ten months because the state's Medicaid program failed to provide the home and community-based services she needed. In November 2016, she was transferred to a nursing home due to this inability to access home-based care despite her doctors' belief that she should not be institutionalized.[351]

As discussed elsewhere in these comments, the ACA dramatically shifted what discrimination in health care and health-related services looks like, especially for non-public health plans.[352] While § 504 allowed various insurance policies that discriminated against people with disabilities, the ACA, which included the reference to § 504 in § 1557, explicitly prohibited many of these same policies.[353] However, institutional bias in covered entity programs and services remains. This includes not only bias towards institutional placements, but bias that prohibits full community integration appropriate to

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[350] *See, e.g., Steimel,* 823 F.3d at 911; *Doe 1 v. Perkiomen Valley Sch. Dist.* No. 22-cv-287, 2022 WL 356868, *18-22 (E.D. Pa. Feb. 7, 2022) (noting § 504 and the ADA impose similar standards and that policies and administrative choices that cause unnecessary segregation because of moving from required to optional masking during the school day constituted disability discrimination). Also, language throughout the Rehabilitation Act of 1973 notes the importance of community integration and the right of people with disabilities to enjoy full inclusion and integration in all aspects of mainstream society. *See, e.g.,* 29 U.S.C. § 701(a)(3)-(6); *see generally* 29 U.S.C. § 701 et seq.

[351] Complaint at 2, 7-8 ¶¶ 3, 29-36, *Vaughn v. Wernert*, No. 1:16-cv-3257 (S.D. Ind. Nov. 30, 2016) (available from NHeLP); *See also* Br. of Appellee at 1-4, *Vaughn v. Walthall*, No. 19-1244 (7th Cir. Feb. 10, 2020).

[352] *See* Amicus Brief of Nat'l Health L. Program et al. in *Doe v. CVS*, *available at* https://healthlaw.org/resource/amicus-brief-from-national-health-law-program-in-cvs-v-doe/ (discussing history of disability discrimination in health coverage and how the ACA changed the landscape, but did so in a way that allows insurers to have nondiscriminatory limitations on coverage and services); *Schmitt v. Kaiser,* 965 F.3d 945, 954-59 (discussing how § 504 may not have prohibited discriminatory benefit design, but the ACA and § 1557 does).

[353] *Id.*

individual needs, such as policies that only cover services if a person is “home bound” or only allows equipment for “at home” rather than for use in the broader community.[354]

Many non-public insurance plans are far more likely to cover a hospitalization but offer limited home care, or they may cover residential treatment for mental health or substance use disorder, but not offer intensive community-based mental health or substance use disorder services that serve as an alternative to institutionalization.[355] Non-public covered entities rarely provide robust community-based services, even when

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[354] As the preamble notes, the integration mandate is not institutionalization versus community living, but the question is one of the most integrated setting appropriate which means a program or activity can be discriminatory if it does support full community integration. *See supra* note 348.

[355] *See* Molly O’ Malley Watts et al., Kaiser Fam. Found., *Medicaid Home and Community-Based Services Enrollment and Spending* (Feb. 4, 2020) (Medicaid fills a gap by covering home and community-based services not typically available through private insurance or Medicare); MaryBeth Musumeci et al., Kaiser Fam. Found., *Medicaid Financial Eligibility in Pathways Based on Old Age or Disability in 2022: Findings from a 50-State Survey* (July 11, 2022), https://www.kff.org/report-section/medicaid-financial-eligibility-in-pathways-based-on-old-age-or-disability-in-2022-findings-from-a-50-state-survey-issue-brief/ (identifying state Medicaid programs that provide buy-in coverage or supplementary coverage; coverage for children of families that may otherwise have health coverage, such as the Katie Beckett option or waiver programs, but who need community-based services); Tami L. Mark et al., *Insurance Financing Increased for Mental Health Conditions but Not for Substance Use Disorders, 1984-2014*, 35 HEALTH AFF. 958, 963 (2016), https://perma.cc/DD66-XFQL (discussing the costs to public insurance of private insurers’ failure to cover mental health and substance use disorder services); Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder,* JAMA NETWORK OPEN (Feb. 5, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032 (discussing the effectiveness of community-based medication assisted treatment versus residential treatment); *see also* Amicus Brief of Nat’l Health L. Program & The Kennedy Forum in *E.W. v. Health Net*, *supra* note 317 (describing the imbalance of publicly provided behavioral health services, including community-based services, compared to private insurance); *see generally* The Kennedy Forum, *Wit v. United Behavioral Health*, https://www.thekennedyforum.org/wit/ (discussing the importance of the case, inappropriate denials of needed behavioral health care, failure to provide care in accordance with generally accepted standards of care, and providing access to some, but not all, of the briefs in the case that provide further information and are incorporated in these comments by reference).

they provide the institutional equivalent.[356] Medicaid is the largest payor of home and community-based services.[357] But this is not simply because more people enrolled in Medicaid need such services or that Medicaid offers more community-based services; in fact, numerous reports show Medicaid does not fully meet the need for community-based services.[358] While Medicaid certainly has populations eligible because of their disabilities or need for care, people often enroll in Medicaid to access community-based services either not covered or not covered sufficiently under non-public health programs and services. Many states include optional Medicaid categories that allow people to have Medicaid, even if they also have insurance through work or other avenues, so that they may access the services they need.[359]

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[356] *See* O'Malley, *supra* note 355.

[357] Watts et al., *supra* note 355.

[358] *See, e.g.,* Molly O'Malley Watts et al., Kaiser Family Found., *State Policy Choices About Medicaid Home and Community-Based Services Amid the Pandemic* (Mar. 2022), https://www.kff.org/report-section/state-policy-choices-about-medicaid-home-and-community-based-services-amid-the-pandemic-issue-brief/; (finding that most states have waiting lists for at least one HCBS waiver with over 665,000 people waiting nationally at any point in FY 2020; notably this number is mostly individuals with intellectual disabilities and most states do not have waiver or similar programs for mental health or other conditions so the waiting list number is not representative of services needed); MACPAC, *Access to Behavioral Health Services for Children and Adolescents Covered by Medicaid and CHIP* 81-93 (June 2021), https://www.macpac.gov/wp-content/uploads/2021/06/Chapter-3-Access-to-Behavioral-Health-Services-for-Children-and-Adolescents-Covered-by-Medicaid-and-CHIP.pdf (discussing lack of services for children with behavioral health needs and likelihood of institutional versus community-based services); *see also* Amicus Brief of Nat'l Health L. Program & The Kennedy Forum in *E.W. v. Health Net*, *available at* https://healthlaw.org/resource/amicus-brief-of-nhelp-and-the-kennedy-forum-in-e-w-vhealth/?fbclid=IwAR3sBc20UO2ZqOhO1GbjHGuJJeboMAQ1T1lmH6K-IynOiIasEBoC5muxFwM (describing the failure of insurers to cover behavioral health services, the history of mental health parity compliance, and cost shifting to public programs).

[359] For example, Medicaid waiver services commonly have higher income limits or do not count the income or assets of parents of minor children with disabilities; have buy-in programs for workers with disabilities; or programs that generally provide supplementary care to those with private health insurance. *See Musumeci et al.*, *supra* note 355. Medicaid is the payor of last resort in such situations, but these Medicaid categories and programs would not exist if private insurance provided the needed services.

Requiring nondiscrimination in benefit design to address community integration may require insurers to make significant changes in their plans, but such changes would be in alignment with the requirements of the ACA. As NHeLP has explained in amicus briefs and elsewhere, the ACA's changing the discriminatory "normal business practices" of the insurance industry does not fairly lead to claims that the ACA and § 1557, if read the way health advocates recommend, would require plans to cover every possible service and give everyone "Cadillac plans." The non-discrimination in benefit design requirements, including the community integration mandate, would do no such thing. They would simply require insurers to design plans, scope of services, and coverage policies in a way that does not discriminate. Plans can still limit services, use utilization review standards, and all the other limitations in their toolboxes to manage costs as long as they are not discriminatory in doing so.[360]

We note that we strongly disagree with the language in the preamble that a covered entity like a state Medicaid program would generally not be required to provide a new benefit because that would fundamentally alter the program.[361] This language, although it includes the qualifier of "generally", is not entirely consistent with case law and could lead to arguments that would unjustly be relied upon by covered entities to limit access

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[360] *See, e.g., Schmitt v. Kaiser*, 965 F.3d at 954-59 (9th Cir. 2020) (discussing how does not require individual plans but imposes an obligation not to discriminate); *see generally* Amicus Brief of Nat'l Health L. Program at al. in *Doe v. CVS*, *supra note* 352 (discussing the obligations of the ACA and ability of plans to use mechanisms they have).

[361] 87 Fed. Reg. 47873; *see, e.g., Steimel,* 823. F.3d at 915 (noting that if every alteration in a program or service that required the outlay of funds was a fundamental alteration, the community integration mandated would be "hollow indeed."); *Radaszeweski ex rel Radaszewski v. Maram,* 383 F.3d 599 (7th Cir. 2004) (community integration mandate may require alteration to services); *Henrietta D. v. Bloomberg,* 331 F.3d 261, 280 (2d Cir. 2003); *see also* U.S. Dep't of Justice, 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.*, at q. 7, https://www.ada.gov/olmstead/q&a_olmstead.htm#_ (last updated Feb. 25, 2020) (entities may be required to provide services beyond what they currently provide); Ltr. from Timothy Westmoreland, Dir. Ctr. for Medicaid & State Operations Health Care Financing Admin. to State Medicaid Dirs. (Jan. 10, 2001) ("Olmstead Ltr. 4"), https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/smd011001a.pdf (discussing obligations to make changes in programs and services to meet the community integration mandate).

to non-discriminatory, integrated care.[362] Specifically, this language distorts well-settled aspects of fundamental alteration analysis and conflates concepts of fundamental alteration, level of benefits, and standard of care in such a way as to potentially improperly limit requiring services, including new benefits or additional benefits.[363] We ask that HHS correct this language in the publishing of the final rule. Although a covered entity may be able to use a fundamental alteration defense to establish that creation of a new service would fundamentally alter their services or otherwise be unreasonable, they may be required to modify existing services or create a new service to avoid discrimination.

For example, a covered entity that provides for services in an institutional setting may have to adapt those services to the community where they have not existed before, including creating coverage policies, provider networks, and other functionalities to ensure that people with disabilities are not forced to go to more segregated settings than are appropriate for their needs to receive the service. In one practical example, an insurer that only provides for residential treatment for certain SUD conditions and does not provide coverage of such services in community-based settings that are clinically appropriate may need to "create" a new benefit in that they have not offered that benefit in the community before, it may go under a different name with different clinical standards, etc. In addition, an entity may have to cover a service that it may want to term as "new" in order to not be discriminatory in coverage even though the service sought is within the existing services being provided.[364]

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[362] *See, e.g., Townsend,* 328 F.3d at 516-521; *Hampe v. Hamos,* 917 F. Supp. 2d 805 (N.D. Ill. 2013); *Lane v. Kitzhaber*, 283 F.R.D. 587 (D. Or. 2012).

[363] *See, e.g., Steimel,* 823 F.3d at 907; *Radaszewski,* 383 F.3d at 615; *Doe v. Kidd*, 419 F. App'x 411 (4th Cir. 2011); *Davis v. Shah,* 821 F.3d 231 (2d Cir. 2016).

[364] Plans already deny services based on coverage discriminatory coverage exclusions that would push needed services into being considered outside of coverage of the plan or potentially "new" to the plan. *See, e.g., Schmitt v. Kaiser,* 965 F.3d 945 (discussing coverage exclusion of certain hearing services); *N.R. v. Raytheon,* 24 F.4th 740 (1st Cir. 2022) (discussing exclusions based on Autism diagnosis); *Duncan v. Jack Henry & Assocs., Inc.,* No. 6:21-CV-03280-RK, 2022 WL 2975072 (W.D. Mo. July 27, 2022) (discussing exclusions for gender affirming surgery compared to other covered surgeries). Furthering the idea or presumption of not having to cover "new" or "services outside the plan" would likely lead to more discriminatory denials.

Ensuring that entities covered by § 1557 have health programs and services that are provided in the most integrated setting appropriate to the needs of qualified individuals with disabilities is critically important and in line with the ACA and § 1557, and § 504 and its interpretations.

§ 92.208 Prohibition on sex discrimination related to marital, parental or family status

We strongly support the Proposed Rule's prohibition on sex discrimination based on "marital, parental, or family status." This provision provides explicit and much needed protections for LGBTQI+ people in non-traditional familial and romantic relationships. For example, this provision would prevent a hospital from refusing to allow a pregnant woman's female partner to accompany her to prenatal visits, while allowing the male partners of other pregnant women to attend prenatal visits. This provision also protects all people from discrimination based on outdated gendered and heteronormative assumptions about family, romantic, and sexual relationships. For example, this provision would prevent a QHP from limiting coverage of contraceptive drugs and devices to married enrollees.[365] It would also prevent a clinician from refusing to perform a sterilization procedure on a man who does not have children because they believe all men should have the chance to be a father.[366]

Support for this provision is clear from examples of some of the problems individuals continue to face:

- After *Dobbs*, a pregnant woman with an ectopic pregnancy had to seek care in another state after being denied treatment in her home state due to providers' worries about providing abortion care, even for an ectopic pregnancy, when the fetus still had cardiac activity.[367]

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[365] *See, e.g., Eisenstadt v. Baird*, 405 U.S. 438 (1972).

[366] *See, e.g.,* Matt Coward, *How Old Do You Have To Be To Get a Vasectomy?*, HEALTHLINE, Jul. 30, 2021, https://www.healthline.com/health/mens-health/how-old-do-you-have-to-be-to-get-a-vasectomy.

[367] Brief for the States of California, New York et al., as Amicus Curiae in Support of Plaintiff's Motion for a Preliminary Injunction at 15, *United States v. Idaho*, No. 1:22-cv-00329 (D. Idaho Aug. 16, 2022). https://portal.ct.gov/-/media/AG/Press_Releases/2022/TexasIdahoBriefs.pdf.

- After *Dobbs*, a pregnant patient in Wisconsin was left bleeding in the hospital for ten days after experiencing a miscarriage before the hospital would remove the fetal tissue because of confusion over the legality of the procedure under state law.[368]

In the preamble to Proposed § 92.208, HHS asks whether it should add a provision to this section that specifically addresses discrimination related to pregnancy or related conditions. We recognize that sex discrimination related to pregnancy or related conditions, including termination pregnancy, can sometimes relate to an individual's current, perceived, potential, or past marital, parental, and family status. However, we urge HHS to not nest sex discrimination related to pregnancy or related conditions under this section of the final rule. We believe that doing so could detrimentally narrow how § 1557's protections against sex discrimination related to pregnancy or related conditions are understood, implemented, and enforced.

Sex discrimination related to pregnancy or related conditions, including termination of pregnancy, is complex and often intersectional. The U.S. has a long sexist, racist, xenophobic, ableist, ageist, and classist history of advancing policies and practices that aim to achieve reproductive control and gender, racial, disability, or other forms of subordination.[369] Current-day health care policies and practices that discriminate against people based on pregnancy or related conditions, including termination of pregnancy, are often about far more than mere marital, parental, or family status. For example, as we discuss above in our comments on Proposed §§ 92.206 and 92.207, health care professionals often dehumanize and medicalize pregnant people and their bodies, and particularly Black pregnant people and their bodies, neglecting requests for pain relief or care for potentially life-threatening pregnancy-related conditions. A health professional's mistreatment of a pregnant immigrant during childbirth, or refusal to provide a Latina woman abortion access as a stabilizing treatment for ectopic pregnancy, may be rooted in discriminatory (and debunked) sexist and white

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[368] *Id.*

[369] *See, e.g.*, Jamila K. Taylor, *Structural Racism and Maternal Health Among Black Women*, 48(3) J. L. MED. & ETHICS (Oct. 2020), https://journals.sagepub.com/doi/full/10.1177/1073110520958875;

supremacist theories that reduce pregnant people to mere fetal vessels.[370]

Instead of Proposed § 92.208, HHS should clarify and add specific provisions on pregnancy or related conditions, including termination of pregnancy, in Proposed §§ 92.8, 92.10, 92.101(a)(2), 92.206(b), and 92.207(b). As we discuss in our comments on Proposed §§ 92.101(a)(2), 92.206(b), and 92.207(b), doing so will enable HHS to address related discrimination more holistically and inclusively in the final rule. We also appreciate HHS's request for comment on what effect, if any, the Supreme Court's decision in *Dobbs* has on implementation of § 1557 and proposed regulations. We respond and describe some of *Dobbs*' vast and detrimental effects on access to a wide range of health services in our comments on Proposed §§ 92.101, 92.206, and 92.207.

§ 92.209 Nondiscrimination on the basis of association

We strongly support the provision of the rule that prohibits discrimination on the basis of association. Consistent with longstanding civil rights law, this provision makes it clear that § 1557's protections extend to discrimination against associates, partners, or family members of protected class members based on that person's race, color, national origin, sex, age, or disability.[371] The proposed language mirrors that of Title I and Title III of the ADA, which protect against discrimination based on association or relationship with a person with a disability, as well as regulatory language implementing Title II of the ADA.[372] This language was included in the 2016 Final Regulations, and then was removed from the 2020 Final Regulations over commenters' protest that the removal would cause confusion both for covered entities and for individuals.[373]

These protections are important because sometimes, the person receiving services from a covered entity is targeted for discrimination because of their association with another person. Preventing this kind of discrimination by association is crucial to addressing health inequities and barriers to care. For example, § 1557's protections

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[370] *See, e.g.*, Alex Samuels & Monica Potts, FIVETHIRTYEIGHT (Jul. 25, 2022), https://fivethirtyeight.com/features/how-the-fight-to-ban-abortion-is-rooted-in-the-great-replacement-theory/.

[371] *See, e.g., Holcomb v. Iona College,* 521 F.3d 130 (2nd Cir. 2008) (Title VII); *Larimer v. International Business Machines Corp*., 370 F.3d 698, 702 (7th Cir. 2004) (ADA).

[372] 42 U.S.C. §§ 12112(b)(4)(Title I); 12182(b)(1)(E)(Title III); 28 C.F.R. § 35.130(g)(Title II).

[373] 85 Fed. Reg. 37-199.

against associational discrimination mean that a pediatrician is prohibited from refusing to make an appointment for a child because their parents are lesbians.[374] A clinic cannot force a pregnant person to wait longer to see their midwife because their doula is Black.[375] It would ensure that a person who is HIV negative and is in a relationship with someone who is HIV positive is not denied access to PrEP.[376] Likewise, it would ensure that a health plan does not fail to offer ASL interpretation to the Deaf caregiver of a hearing family member who is undergoing necessary surgery, and it clarifies that a covered entity cannot compel a family member or friend to provide ASL interpretation or reasonable accommodations.[377]

The Proposed Rule also accurately reflects Congress' intention for § 1557 to provide at least the same protections for patients and provider entities. In accordance with the ADA, the current regulation recognizes this protection extends to providers and caregivers, who are at risk of associational discrimination due to their professional relationships with patients, including those patient classes protected under § 1557.[378] For example, health insurers are prohibited from refusing a provider's application to join a plan network because that provider chooses to work with populations that are more likely (or perceived to be more likely) to acquire chronic infectious diseases. Likewise, health insurers cannot discriminate against providers who prescribe medication assisted treatment due to their association with individuals with a history of substance use

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[374] Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal About It*, WASH. POST, Feb, 19, 2015, https://www.washingtonpost.com/news/morning-mix/wp/2015/02/19/pediatrician-refuses-to-treat-baby-with-lesbian-parents-and-theres-nothing-illegal-about-it/.

[375] *See, e.g.,* Juan Salinas et al., *Doulas, Racism, and Whiteness: How Birth Support Workers Process Advocacy towards Women of Colo*r, 12 SOCIETIES 19 (2022).

[376] *See, e.g.,* Eli Latto, *HIV-Serodiscordant Couples, Pre-Exposure Prophylaxis and Relationship Satisfaction,* Masters Thesis, Smith College at 13 (2016), https://scholarworks.smith.edu/cgi/viewcontent.cgi?article=2800&context=theses.

[377] *See, e.g.,* Leila Miller, *'I was panicked': Deaf Patients Struggle to Get Interpreters in Medical Emergencies*, STAT., May 22, 2017, https://www.statnews.com/2017/05/22/deaf-patients-interpreters; *Loeffler v. Staten* Island Univ. Hosp., 582 F.3d 268, 279 (2d. Cir. 2009) (permitting discrimination claim brought by Deaf father's children who were forced to interpret for him in the hospital).

[378] 28 C.F.R. pt. 35, app. B (2015) (interpreting Title I and Title III of the ADA to protect "health care providers, employees of social service agencies, and others who provide professional services to persons with disabilities").

disorder. Under § 1557, these examples are both forms of disability-based associational discrimination.[379]

§ 92.210 Nondiscrimination in the use of clinical algorithms in decision-making

The role of algorithms and other forms of automated decision-making systems (ADS) have long been recognized as a source of bias, discrimination, and wrongful denial of necessary care. We support Proposed § 92.210 in recognizing covered entities cannot discriminate through the use of clinical algorithms and that this is a problem that needs to be addressed.[380] However, the focus on "clinical algorithms" misses the numerous ways in which algorithms and other ADS harm individuals through logistical issues, measurement issues, various sources of data bias, discriminatory decisions throughout the lifecycle of an ADS, and problems with policies and processes around an ADS.[381] NHeLP has a long history of fighting against harmful clinical tools by entities that would be covered by § 1557, including the increased use of ADS to deny care or otherwise harm individuals, including in discriminatory ways.[382] While we support the inclusion of §

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[379] *Mx Group, Inc. v. City of Covington*, 283 F.3d 326, 335 (6th Cir. 2002) (holding a drug and alcohol treatment center that was denied a zoning permit because it provided services to individuals with disabilities was subjected to discrimination under Title II of the ADA).

[380] Proposed Rule, 87 Fed. Reg. 47880-84.

[381] *See generally* Benefits Tech Advocacy Hub, *Making Sense of Technology Problems Framework*, https://www.btah.org/resources/making-sense-of-technology-problems-framework (describing logistical issues, measurement issues, and other problems with ADS and how it shows up in practice); *Understanding the Lifecycle of Benefits Technology*, https://www.btah.org/lifecycle.html (describing the lifecycle stages and the possibilities for bias and issues throughout the process; including the individual page for each lifecycle phase such as devising); *Case Study Library*, https://www.btah.org/case-studies.html (providing examples of harm from ADS in public benefits); *Resources List*, https://www.btah.org/resources.html (providing resources that describe various issues with ADS, harm to individuals, litigation, and additional articles on the reading list for more examples, all of which we incorporate by reference); Aaron Rieke, Miranda Bogen & David G. Robinson, Upturn & Omidyar Network, *Public Scrutiny of Automated Decisions: Early Lessons and Emerging Methods* 5 (2018), https://omidyar.com/wp-content/uploads/2020/09/Public-Scrutiny-of-Automated-Decisions.pdf (describing opportunities for bias and human influence throughout the development of technology).

[382] *See* Elizabeth Edwards, Nat'l Health Law Program, *Preventing Harm from Automated Decision Making Systems in Medicaid* (June 14, 2021), https://healthlaw.org/preventing-harm-

92.210, we request that HHS define the term "clinical algorithm" and do so broadly, or change the term so that it includes the various ways covered entities may discriminate against individuals using ADS. Doing so is necessary to avoid narrow definitions of "clinical algorithms" and subsequent limited protections from harmful ADS. We also discourage HHS from creating safe harbors or other policies that set standards for accountability. While we recognize this is an area that would benefit from increased regulation, most of the current proposals we are aware of are insufficient and are often harmful given that these gaps frequently overlook the rights of many individuals.

A. The Term "Clinical Algorithm" Does Not Encompass the Harm the Proposed Rule Intends to Prevent or is Required by Section 1557

The term "clinical algorithm" as used in Proposed § 92.210 is not defined in that section nor in the definitions at Proposed § 92.4. Although the preamble lists numerous examples of harmful ADS tools used by covered entities, some may not consider all of these tools to be clinical algorithms either because they are not used to make clinical decisions or because they are not algorithms.[383] For example, the preamble describes the crisis standard of care tools used during the COVID-19 pandemic as "formal guidelines or policies" and then later describes some of the assessment tools that were part of some of these very discriminatory policies.[384] But not all of these challenged policies were algorithms in the classic sense because not all of those that were complained about as discriminatory drove a standardized decision. Instead some of the discriminatory policies were more guidelines. Under a broad definition of the term algorithm, such tools, policies, and processes would be included even if they do not

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from-automated-decision-making-systems-in-medicaid/ (discussing examples of harm and citing through hyperlinks and related resources other examples harmful ADS and sources of bias, including related cases); Elizabeth Edwards et al., Nat'l Health Law Program, *Comments in Response to the AHRQ RFI on the Use of Clinical Algorithms that have the Potential to Introduce Racial/Ethnic Bias into Healthcare Delivery* (May 4, 2021), https://healthlaw.org/resource/nhelp-ahrq-comments/ *as incorporated and added to in comments to NIST by* Elizabeth Edwards, Nat'l Health Law Program, *Comments on NIST Proposal for Identifying & Managing Bias in AI* (Sept. 15, 2021), https://healthlaw.org/resource/comments-on-nist-proposal-for-identifying-managing-bias-in-ai/ (hereinafter "NHeLP AHRQ & NIST Comments").

[383] 87 Fed. Reg. 47881-5.

[384] *Id.* at 47881-82.

require a predictable outcome but instead guide a decision making process. But a stricter definition of clinical algorithm would limit this section to the more formal, restrictive tools that result in a score or a decision that has limited subjectivity in its use. A limited definition of clinical algorithm or any replacement term that is narrow would leave out so many of the discriminatory ADS used by covered entities. The regulatory language about decisions made based on discriminatory algorithms should be broad and inclusive of the different types of decision tools and the types of problems they may have.

ADS is rife in health care programs and activities of covered entities. Over our 50-year history, we have identified numerous examples of harmful ADS in Medicaid and health care generally. NHeLP advocacy has addressed problems with some of the earliest eligibility computer systems to current eligibility systems, with the use secret utilization control standards, with the use of unconstitutional processes around assessment tools for home and community-based services, and with denials of care based on fiscal reasons rather than clinical ones. Numerous examples exist identifying bad systems; systems implemented without sufficient testing; discrimination in design, implementation, and process; discriminatory data sources; and other issues.[385] For example, Arizona's Medicaid eligibility systems was wrongfully reducing full scope benefits to emergency-only benefits because the eligibility ADS was overwriting critical information about immigration status.[386] In other examples of bad programming or design, Medicaid beneficiaries in Wisconsin and Arkansas saw improper terminations and cuts to services.[387] There are numerous examples of discriminatory ADS outside of

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[385] *See supra* notes 381, 382 (citing resources that describe and also link to additional resources, such as the Benefits Tech Advocacy Hub Case Studies and NHeLP's resources and case list linked to the NHeLP AHRQ & NIST Comments, about NHeLP's experience with and knowledge of harmful ADS).

[386] Nat'l Health Law Program, *Darjee v. Betlach*, District of Arizona (July 22, 2016), https://healthlaw.org/resource/darjee-v-betlach-united-states-district-court-district-of-arizona/ (providing pleadings and summary of the case).

[387] Benefits Tech Advocacy Hub, *Case Studies,* Arkansas, https://www.btah.org/case-study/arkansas-medicaid-home-and-community-based-services-hours-cuts.html & Wisconsin, https://www.btah.org/case-study/wisconsin-medicaid-home-and-community-based-services-terminations.html.

Medicaid, including tools that deny or limit care, or try to identify fraud or other "bad actors" and instead cause improper limitations on care.[388]

Harm, including discrimination, from ADS is not just limited to bad programming or design. As described in NHeLP's AHRQ Comments, ADS problems are generated by decisions throughout the lifecycle of ADS.[389] Institutional bias is deeply embedded in in health care, including explicit and implicit bias, and typically centers the white, heteronormative experience.[390] This bias is throughout systems, including the research

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[388] *See, e.g.,* Maia Szalavitz, *The Pain Was Unbearable, So Why Did Doctors Turn Her Away?,* WIRED (Aug. 11, 2021), https://www.wired.com/story/opioid-drug-addiction-algorithm-chronic-pain/ (denial of care due to algorithm that flagged a woman with chronic pain as a drug seeker because of pet's medications); Skyler Rosellini, Nat'l Health L. Program, *Limited Data Collection for LGBTQI+ Health Promotes Bias* (June 22, 2021), https://healthlaw.org/limited-data-collection-for-lgbtqi-health-promotes-bias/ (describing how "gender conflicts" lead to misdiagnoses and discrimination in health care settings); Kendra Albert & Maggie Delano, *Sex Trouble: Sex/gender slippage, sex confusion, and sex obsession in machine learning using electronic health records,* PATTERNS, Aug. 12, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9403398/ (discussing false assumptions regarding sex in medical data and the resulting problems); Laleh Seyyed-Kalantari *et al.*, *Underdiagnosis Bias of Artificial Intelligence Algorithms Applied to Chest Radiographs in Under-Served Patient Populations,* NATURE (Dec. 10, 2021), https://www.nature.com/articles/s41591-021-01595-0; Milena A Gainfrancesco *et al.*, *Potential Biases in Machine Learning Algorithms Using Electronic Health Record Data,* 178 JAMA INTERN. MED. 1544-47 (Jan. 25, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6347576/; *see also Wit v. United Behavioral Healthcare*, 14-cv-2346-JCS, 2019 WL 1033730 (N.D. Cal. July, 27, 2020) (although not explicitly an ADS, discovery into utilization management tools found that the criteria used did not align with clinically accepted criteria and was unduly influenced by fiscal rationales); The Kennedy Forum, *A Breakdown of United Healthcare's Recent Parity Settlements* (Aug. 24, 2021), https://www.thekennedyforum.org/blog/a-breakdown-of-unitedhealthcares-recent-parity-settlements/ (describing role or algorithm in an "Alert Program" that improperly led to utilization review and denied care); *see generally* NHeLP AHRQ & NIST Comments, *supra* note 385.

[389] NHeLP AHRQ & NIST Comments, *supra* note 385.

[390] *Id.* at 12; *see, e.g.,* Ibram x. Kendi, *There is No Such Thing as Race in Health-care* Algorithms, 1:8 THE LANCET E375 (Dec. 2019), https://www.thelancet.com/journals/landig/article/PIIS2589-7500(19)30201-8/fulltext; Rachel R. Hardeman, Eduardo M. Medina & Katy Kozhimannil, *Structural Racism and Supporting Black Lives—The Role of Health Professionals*, 375 NEW ENG. J. MED. 2113 (Dec. 1, 2016) (summarizing sources of bias in health care).

that is often cited as objective bases of ADS.[391] ADS used in health care program and activities as covered by § 1557 is often some type of assessment tool that involves assigning values to information to analyze based on formulas, decision trees, or other tools with the system, to result in a score or other output that is assigned meaning. These systems inherently have humans and their bias making decisions throughout the ADS lifecycle and using data, research, and presumptions that are likely biased.

At the heart of many ADS used in health care is statistical analysis based in research. While this may sound objective, it is certainly not free from the bias that exists at every step of the process as does the institutional biases in health care. As demonstrated by the examples in the preamble and the references cited in these comments, there is often bias in who participates in clinical research, who performs research, and the underlying data.[392] Throughout history, access to health care has largely been a privilege and not a right, meaning many people have been excluded or underrepresented in the health care system. This means that the data underlying most ADS is skewed in similar ways, often resulting in bias. There are also biased assumptions built into many ADS, like those in the NFL's brain injury tests regarding race and cognitive function or the those in the crisis standards of care policies about the

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[391] *See, e.g.,* Rhea Boyd et al., *The World's Leading Medical Journals Don't Write About Racism. That's a Problem,* TIME (Apr. 21, 2021) (finding that the top four medical journals in the world almost never publish scientific articles that name racism as a driver of poor health outcomes and less than 1% of the 200,000 articles published over the past 30 years included "racism" anywhere in the text; of the few articles that did, 90% were predominately opinion pieces); Usha Lee McFarling, *When a Cardiologist Flagged the Lack of Diversity at Premier Medical Journals, the Silence was Telling,* STAT (Apr. 12, 2021), https://www.statnews.com/2021/04/12/lack-of-diversity-at-premier-medical-journals-jama-nejm/ (discussing the impact on research from the lack of diversity at premier medical journals); Brandon E. Turner et al., *Race/ethnicity Reporting and Representation in US Clinical Trials: A Cohort Study,* 11 THE LANCET REGIONAL HEALTH – AMERICAS 1 (July 2022), (https://www.sciencedirect.com/science/article/pii/S2667193X22000692?via%3Dihub); *see generally* Mary May, Harvard Univ. SITN, *Racism and Exploitation in Phase I Clinical Trials* (Oct. 4, 2020), https://sitn.hms.harvard.edu/flash/2020/racism-and-exploitation-in-phase-i-clinical-trials/. For an example of bias in inputs, how ADS interpret natural language can be rife with bias, *see* Oliver J. Bear Don't Walk, IV et al., *A Scoping Review of Ethics Considerations in Clinical Natural Language Processing,* JAMIA OPEN (July 5, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9154253/.

[392] *See supra* note 388; NHeLP AHRQ & NIST Comments, *supra* note 385.

value of the lives of people with disabilities and quality adjusted life years (QALYs).[393] The institutional bias in health care is so ingrained that removing factors such as race from an ADS does not solve the problem due to the proxy discrimination from other factors. For example, removing race but relying on zip codes is not going to make the ADS unbiased due to the institutional bias in housing, land use, and environmental hazards.[394] Or removing race from the VBAC calculator may not resolve racial bias in the tool.[395] The problems with institutional bias and proxy discrimination have long been recognized in problematic health care, insurance, housing, criminal, and financial algorithms.[396] In addition, because tools are often based on statistical analyses, this means that there will be people who are the exception just like there were outliers in the original data. This can create discrimination and disparately impact groups.[397]

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[393] *See* NHeLP AHRQ & NIST Comments, *supra* note 385, at 14-16; Proposed Rule, 87 Fed. Reg. 4780-82.

[394] *See, e.g.,* Amaya Taylor, Urban Inst., *The Connection between Housing, Health and Racial Equity* (May 12, 2021); Dayna Bowen Matthew et al., Brookings Inst., *Time for Justice: Tackling race inequalities in health and housing* (Oct. 19, 2016), https://www.brookings.edu/research/time-for-justice-tackling-race-inequalities-in-health-and-housing/. For example, using zip codes rather than race would not eliminate racial bias when applied to people involved in issues like the Flint water crisis, East Calumet lead superfund site, or “cancer alley” along the Mississippi River. Housing has long been recognized as relevant to health and health outcomes. *See, e.g.,* Lauren Taylor, *Housing and Health: An Overview of the Literature,* HEALTH AFF. (June 7, 2018), https://www.healthaffairs.org/do/10.1377/hpb20180313.396577/.

[395] *See, e.g.,* Nicholas Rubashkin, *Why Equitable Access to Vaginal Birth Requires Abolition of Race-Based Medicine,* AMA J. ETHICS (Mar. 2022), https://journalofethics.ama-assn.org/article/why-equitable-access-vaginal-birth-requires-abolition-race-based-medicine/2022-03.

[396] *See, e.g.,* Anya E.R. Prince & Daniel Shwarcz, *Proxy Discrimination in the Age of Artificial Intelligence and Big Data*, 105 Iowa L. Rev. 1257 (2020), https://ilr.law.uiowa.edu/print/volume-105-issue-3/proxy-discrimination-in-the-age-of-artificial-intelligence-and-big-data.

[397] For example, in the Medicaid context, assessment tools are commonly used to determine the amount of services that will be provided to keep them in the community rather than in an institutional setting, as required by *Olmstead.* But often these tools, such as SIS and InterRAI, because they are built on statistical analysis, do not fully capture an individual’s needs. The creator of SIS, AAIDD, recommends an exceptions process any time a state uses the tool for budget or service allocation. But the use of these tools, including the lack of an exceptions process or access to it has been the subject of multiple lawsuits. *See, e.g, Brandy C. v. Palmer*,

Section 1557 clearly prohibits discrimination, and that would include any discrimination by ADS. Bias in ADS is a significant problem in health care programs and activities and covered entities should not be able to escape responsibility for discriminatory decisions, outcomes, or other impacts made based on or that includes information from ADS.

B. HHS Should Not Recognize Any ADS Defenses or Safe Harbors

We caution against the recognition of any defenses or safe harbors for the use of ADS by covered entities. Best practices in algorithmic accountability and justice are quickly evolving. It is important that § 1557's protections remain broad and not prematurely limited. As discussed above and in many of the articles referenced, institutional bias and proxy discrimination in ADS are serious problems and clear, reliable fixes to these problems have not yet been identified. Recognizing any defenses for the use of ADS by covered entities is likely to set a dangerously low bar that would allow ongoing discrimination or allow entities to escape the very liability that may be necessary to remediate bias in health programs and activities. HHS should learn from the comments provided when HUD proposed a rule that would allow defenses based on the use of algorithms in housing. During that process, commenters provided in depth examples of how deeply embedded bias is in housing algorithms and algorithms generally, and the dangers of allowing defenses based on variations of "the computer did it."[398] HHS

No. 4:17-CV-226, 2018 WL 4689464, (N.D. Fla. Sept. 29, 2018) (particularly the expert reports citing the underfunding of services by the assessment tool); *Belancio v. Kansas Dept of Health and Environment*, No. 17-CV-1180, 2018 WL 4538451 (D. Kan. Sept. 21, 2018); *K.W. v. Armstrong*, No. 1:12-cv-00022, 2016 WL 1254225 (D. Idaho Mar. 28, 2016); *Waldrop v. New Mexico Hum. Servs. Dep't*, No. CV 14-047 JH/KBM, 2015 WL 13665460 (D.N.M. Mar. 10, 2015); *L.S. by & through Ron S. v. Delia*, No. 5:11-CV-354-FL, 2012 WL 12911052 (E.D.N.C. Mar. 29, 2012); Benefits Tech Advocacy Hub, *Case Study Library*, https://www.btah.org/case-studies.html; *see also* U.S. Dep't Justice, Maine Home and Community-Based Services (June 2021), https://www.justice.gov/crt/case/maine-home-and-community-based-services (finding Maine discriminated against an individual by failing to include an exceptions process). Numerous Medicaid cases have challenged policies and assessments that lead to insufficient services. *See generally* Nat'l Health L. Program, Defending & Advancing Health Rights in Court, https://healthlaw.org/our-work/litigation/ (listing Medicaid and related litigation).

[398] *FR-6111-P-02 HUD's Implementation of the Fair Housing Act's Disparate Impact Standard*, https://www.regulations.gov/document/HUD-2019-0067-0001/comment (posting the proposed rule as well as comments submitted). Although all of the comments are relevant for HHS's

should also learn from the compliance issues related to mental health parity in terms of the complexity of discrimination by design, including algorithms, and problems with disclosure and transparency.[399] These lessons also indicate how important it is that external reviews and oversight of compliance that are proactive rather than simply reactive are necessary to identify and correct bias and harm from ADS.

Ideas about algorithmic accountability and justice vary widely and are inconsistent, but a common theme is ignoring certain legal rights.[400] Importantly, many of the proposals fail to recognize that constitutional due process requires transparency that is often only

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evaluation of this provision, comments from organizations such as Upturn, EFF, AI Now, Center for Democracy & Technology, Center for Responsible Lending, NHeLP, and FTC Commissioner Rohit Chopra may be particularly helpful).

[399] *See supra* § 92.207 section G (discussing the history of Mental Health Parity compliance, role of disclosure, and ongoing issues)*; see also* Amicus Brief of Nat'l Health L. Program & The Kennedy Forum*, supra note 317* (discussing Mental Health Parity compliance history and challenges); N.R. v. Raytheon, 24 F.4th 740 (discussing the challenges with disclosure requirements).

[400] *See, e.g,* NHeLP AHRQ Comments, *supra* note 3 (noting problems with AHRQ's proposal and the later proposal by NIST); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-21-519SP, ARTIFICIAL INTELLIGENCE: AN ACCOUNTABILITY FRAMEWORK FOR FEDERAL AGENCIES AND OTHER ENTITIES (2021), https://www.gao.gov/assets/gao-21-519sp.pdf. Notably, figuring out algorithmic accountability is a problem worldwide and even though certain countries, like some in Europe, have more laws around the use of algorithms, advocates run into similar problems and there are still significant questions about the best approach to ensuring fairness and justice when ADS is used. *See, e.g.,* Melissa Heikkila, *The EU Wants to Put Companies on the Hook for Harmful AI,* MIT TECH. REV. (Oct. 1, 2022) (discussing problems enforcing algorithmic fairness in the EU and new efforts to correct these issues but the unknown impact), https://www.technologyreview.com/2022/10/01/1060539/eu-tech-policy-harmful-ai-liability/; Rashida Richardson et al., AI Now Inst., *Litigating Algorithms 2019 US Report: New Challenges to Government Use of Algorithmic Decision Systems* (Sept. 2019), https://ainowinstitute.org/litigatingalgorithms-2019-us.pdf (discussing U.S. litigation regarding algorithms as well as a case from the Netherlands); Nani Jensen Reventlow, Digital Freedom Fund, *Litigating Algorithms: Taking the conversation from North America to Europe and beyond* (Nov. 18, 2019) (discussing problems with holding technology accountable in various counties and linking to other articles about limitations of existing accountability mechanisms); *see generally* The Atlas Lab, https://www.atlaslab.org/articles/categories/case-studies (discussing problems with algorithm accountability, litigation, case studies, etc.).

"recommended" in algorithmic accountability policy solutions.[401] When services have constitutional due process rights attached, any decision to reduce, deny, or terminate those services must, among other things, be explained to individuals in such a way that they understand the decision made about them and provide them sufficient information such that they know what they are appealing. An explanation that an assessment determined an individual will receive a certain number of hours or that the utilization review tool denied a service is insufficient.[402] And yet, ADS is used in health care all the time, including on Medicaid patients, in ways that they are not aware of or not given explanation about. Similarly, accountability proposals often overlook rights such as the community integration mandate or other non-discrimination protections.

Transparency, which is commonly part of algorithmic accountability, is critical but cannot be the answer for multiple reasons, including that transparency puts the burden on individuals to understand the ADS, have expertise to challenge it, and have the resources to do so. This is too great of a burden to put on individuals when the covered entities are the ones benefit from the use of the ADS and others, such as developers, have profited from the creation. Although there should not be an expectation that transparency solves certain issues, it remains important. Covered entities should be required to disclose, without request, they areas in which they use ADS, the populations affected, what the ADS does, how it has been and continues to be tested for bias, how the input for the ADS is gathered, and how the output is used in decision making, including any identified limitations and how much discretion the decision maker has. There must be protective steps throughout the ADS's lifecycle, including around the processes used around the ADS to ensure that the ADS does not create harm. This includes how the covered entity uses databases, EHR, demographic data, etc. gathered

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[401] *See, e.g.,* NHeLP AHRQ & NIST Comments, *supra* note 385 (noting problems with the approach proposed by AHRQ for accountability and subsequently by NIST); Jane Perkins, Nat'l Health L. Program, Demanding Ascertainable Standards: Medicaid as a Case Study (2016), https://healthlaw.org/resource/demanding-ascertainable-standards-medicaid-as-a-case-study/ (describing the constitutional right to ascertainable standards for decisions made about public benefits, including Medicaid services); *see also* Jane Perkins, Nat'l Health Law Program, *Q&A: Using Assessment Tools to Decide Medicaid Coverage* (June 9, 2016), https://healthlaw.org/wp-content/uploads/2016/06/QA-Case-deelopments-May-20162.pdf; Jane Perkins, Nat'l Health Law Program, *Ensuring that Assessment Tools are Available to Enrollees* (Sept. 10, 2015), https://healthlaw.org/resource/ensuring-that-assessment-tools-are-available-to-enrollees/.

[402] *See, e.g., supra* note 397; *see also, e.g., Unan v. Lyon*, 853 F.3d 279 (6th Cir. 2017).

from beneficiaries in their systems and assurances that such sources of information adequately gather information at needed levels of granularity to identify bias and promote health equity. It is also important that affected individuals give informed consent about how their data is used by an entity.

Transparency also has the challenge of trade secret protections, which are frequently asserted when advocates want to inspect ADS.[403] As mentioned earlier, lessons learned from mental health parity compliance around disclosure and access to underlying documents, including those protected by trade secret provisions, can help guide HHS about the types of problems that may surround ADS accountability. But overall, the accountability proposals typically do not adequately address these issues and we discourage HHS from making statements about minimum standards for ADS unless they can do so without potentially harming individuals affected by the ADS and their rights.

Problematically, most of the algorithmic accountability proposals fail to adequately account for the experience of individuals in the system nor do these proposals center individuals at all, even though they are the most likely to be harmed. Accountability proposals are often systems approaches trying to identify problems and correct them within the ADS itself or its design. But these systems are denying necessary care to individuals and it is those individuals that should be centered in any theories of algorithmic accountability. Centering the individual would help ensure they understand when an automated process is being used that may not correctly take into account their individual needs, that they have the necessary information to appeal any decision made against them, and that they can ask for an exception when needed to account for individual differences, intersectional identities, and bias in the systems. But ensuring the

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[403] *See, e.g., Salazar v. Dist. of Columbia*, 596 F. Supp. 2d 67 (D.D.C. Feb. 6, 2009) (copyright law and local trade secret laws do not trump the federal Medicaid statute and regulations); *Ark. Dept. of Commerce, Div. of Workforce Servs. v. Legal Aid of Ark,* 645 S.W.3d 9 (S.C. Ark. 2022) (finding that unemployment claimants are not competitors for the purpose of the proprietary information exception and granting access to algorithm and related information requested through freedom of information act request to state); *Kate Crawford & Jason Schultz*, *AI Systems as State Actors*, 119 Columbia L. Rev. 1941 (2019), https://columbialawreview.org/content/ai-systems-as-state-actors/; Yale Law School, *Algorithmic Accountability*, https://law.yale.edu/mfia/projects/government-accountability/algorithmic-accountability (report and posted documents reveal problems with trying to access algorithms).

individual can raise their hand and object to the decision should be the last step in a system that has sufficient processes and protections in place to test the ADS for harm before it is operational and in an ongoing way after it is put in place.

We support Proposed § 92.210, but recommend HHS define "clinical algorithm" or use a different term that will encompass all the ADS used by covered entities and the potential harm from them. In response to HHS's various questions about what further information to provide around clinical algorithms, we ask HHS to take into consideration our concerns on algorithmic accountability and in no way limit the ability of affected individuals and groups to challenge discrimination that is caused in any way by decisions covered entities make when using ADS.

§ 92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services

NHeLP supports inclusion of a provision on telehealth and for recognizing it as a tool to improve access for patients who, for various reasons, are unable or prefer to receive services in person. Such need has been highlighted during the COVID-19 pandemic, when telehealth proved to be a life-saver for people across the country.[404] The National Health Law Program defines telehealth as the use of digital technology to deliver health care, health information, and other health services, including diagnosis, treatment, assessment, monitoring, communications, and education.[405]

We agree that clarifying that nondiscrimination requirements must apply to telehealth services but recommend specific requirements related to access for individuals with LEP and individuals with disabilities. While telehealth has been useful for all populations, studies indicate that LEP patients participate in a significantly lower percentage of video visits compared with the percentage of patients who typically receive primary health care services.[406] Similarly, research confirms that telehealth access is not equitable across different population subgroups, like people with

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[404] See *e.g*., Sanuja Bose et al., *Medicare Beneficiaries In Disadvantaged Neighborhoods Increased Telemedicine Use During The COVID-19 Pandemic*, 41 HEALTH AFF. 1 (May 2022).
[405] Fabiola Carrion, Nat'l. Health Law Prog., *Medicaid Principles on Telehealth* (May 11, 2020), https://healthlaw.org/resource/medicaid-principles-on-telehealth/.
[406] See *e.g*., https://www.rand.org/pubs/research_reports/RRA1840-1.html.

disabilities.[407] A national study confirmed that telehealth service platforms are not yet made available at all to people with disabilities or people with limited English proficiency.[408]

We believe that providers, advocates, and users would benefit from specific provisions addressing accessibility in telehealth services and particularly related to access for individuals with disabilities and LEP individuals. While we understand that different providers and patients will have different needs and require different tools, as a first step, providers should attest to doing their best to accommodate their patients' needs while patients should confirm that they have everything available to fully participate in the telehealth interaction. Some of these accommodations will also have to be afforded according to the type of telehealth modality. For instance, an accommodation for someone who is using audio-only services would be different if that same patient was using synchronous, video-conferencing telehealth. Telehealth platforms should also be designed to attend to the needs of these various populations.

As with in-person services, services delivered through telehealth should be culturally and linguistically competent. To this end, qualified interpreters, readers and bilingual/multilingual employees should be available to individuals accessing care through telehealth.[409] Every portal, software, or document that is part of the patient's telehealth experience should be professionally translated into a state threshold language. Similarly, specific adjustments must also be made for people with disabilities. Platforms should be adopted to meet the needs of people who are neurodivergent, deaf or hard of hearing, blind, movement impaired, or otherwise unable to communicate via traditional telehealth models. Before the telehealth interaction, providers should assess for visual, cognitive, intellectual, mobility as well as functional needs in order to

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[407] Madjid Karimi et al., *HHS Office of Health Policy, National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services* (Feb. 1, 2022) (hereinafter "National Survey Trends in Telehealth Use in 2021"), www.aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telehealth-hps-ib.pdf.

[408] *Id.*

[409] *Medicaid Principles on Telehealth, supra* note 405.

maximize the patient's health care experience.[410] Finally, we understand that telehealth is dramatically changing the way that telehealth is delivered for the majority of Americans. As such, we strongly encourage the development of more research that analyzes telehealth experiences, particularly for underserved populations like LEP individuals and people with disabilities, and that these lessons allow providers, health systems, and other stakeholders to adapt accordingly and continuously.
Finally, given that telehealth is incorporated in "communication technology for individuals with disabilities (Proposed § 92.204), it would be helpful to explain the interaction between these two sections.

Similar issues arise for people with disabilities. Disabilities and health conditions, even the same diagnosis, can have wide variance in their particular functional impact on disabled individuals, who themselves vary widely in their physical, educational, cultural, and socio-economic backgrounds. Someone who has aged into hearing loss and someone who is culturally Deaf and fluent in American Sign Language have different communication needs. Both might encounter barriers to using telehealth but for different reasons: an older person might need assistance with video call technology in her home and prefer to call in using her own amplified phone during the video call so she can speak with a provider while the Deaf person needs the provider's proprietary video call technology to seamlessly integrate a pinned ASL interpreter with the video screen so they can simultaneously follow a provider's facial expressions and demonstrations while seeing what the provider is saying.

Telehealth offers patients several advantages: an appointment usually can be obtained sooner, healthcare can be obtained in the privacy of one's home without exposure to viruses or having to interact with strangers, transportation costs can be avoided, and it may be possible to forego losing wages for lost hours or having to make childcare arrangements. But these advantages are lost if telehealth fails to conceptually and practically accommodate those whose bodies or minds work in different ways, who need to see language rather than speak it, who need to touch or hear information rather than read it, or who do not have fine motor control for controlling common video technology or medical monitoring devices. While information and communication

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[410] NCQA & Janssen, *The Future of Telehealth Roundtable: The Potential Impact of Emerging Technologies on Health Equity,* https://www.ncqa.org/wp-content/uploads/2022/05/NCQA-TelehealthAndEquity-Whitepaper-Draft5.pdf, pg. 11.

technology (ICT) are an integral part of effective health care, health care programs and activities consist of more than just information and communication. Proposed § 92.211 recognizes that telehealth is not just an alternate form of communication, but a distinct health care activity that needs to accessible to individuals no matter a person's language, how a person's body functions, the language used, and the person's cultural or socio-economic context.

A telehealth visit does not automatically equal an office visit just because the same parties face each other over a screen. The impact of differences in health and wellness screening are likely to be felt most keenly by individuals with chronic conditions such as diabetes and Chronic Obstructive Pulmonary Disease. Telehealth can incorporate patient reporting of health statistics using mobile applications or "at-home tools" that enable a person to find their own blood pressure, pulse rate, blood sugar level, oxygen saturation rate, and even basic weight. But if the home replacement tools for the kind of monitoring that routinely happens at a healthcare provider's office are not accessible to individuals with disabilities or LEP, then the entire telehealth visit is less reliable and useful. An in-person visit can also efficiently mix complementary preventive services, such as administering vaccines during a well-child exam, or making lab referrals and booking laboratory appointments or additional vision tests immediately after an office exam. A telehealth visit that attempts to take the place of what can be done in person can involve a higher degree of patient involvement, activity, and initiative such as using at-home glucose monitors and taking bodily fluid samples and sending them safely and securely to a lab.

The job of figuring out how these activities can be accomplished logistically, efficiently, and accessibly through telehealth cannot be placed on individuals or their families. Covered entities must be responsible for ensuring that telehealth visits, which can often include real time interaction, pre-preparation monitoring and follow-up activity, provide equally effective care to all individuals regardless of "race, color, national origin, sex, age, or disability."

We thus recommend HHS require telehealth platforms must be able to include a third party such as an interpreter or use of auxiliary aids and services. Second, all of the communication about telehealth that occurs prior to a telehealth appointment – including scheduling, information about system requirements and testing connections, appointment reminders, and log-on details – must be accessible to people with LEP and disabilities. Similarly, platforms should be adapted to meet the needs of people who are autistic, deaf or hard of hearing, blind, deaf/blind, movement impaired, or otherwise have difficulty in communicating via traditional telehealth models. As noted by NCQA, before a telehealth interaction, providers should assess for visual, cognitive, intellectual, mobility as well as functional needs to maximize the patient's health care experience.[411]

We also suggest OCR consider including notification of telehealth services in the list of electronic communications that must include the notice of availability of language assistance services and auxiliary aids and services.

SUBPART D – PROCEDURES

§ 92.301 Enforcement mechanisms

We support the proposed changes restoring language from the 2016 Final Rule. However, we urge HHS to further explain how it will address intersectional claims when people experience discrimination on more than one basis. Moreover, HHS should clarify that the full range of enforcement mechanisms and remedies is available to any person pursuing a discrimination claim under § 1557, regardless of their protected class.

Congress intentionally designed § 1557 to build and expand on prior civil rights laws such that individuals seeking to enforce their rights would have access to the full range of available civil rights remedies and not be limited to only the remedies provided to a particular protected group under prior civil rights laws. Section 1557 expressly provides individuals access to any and all of the "rights, remedies, procedures, or legal standards available" under the cited civil rights statutes, regardless of the type of discrimination.

Some courts have interpreted § 1557 to apply different enforcement mechanisms and standards depending on whether someone's claim is based on race, sex, age, or disability. These cases assume that Congress meant to tether the standards and enforcement mechanisms available based on the statute that defines the grounds for

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[411] *Id*.

discrimination.[412] But the courts in these cases misconceive the statutory language and context.

HHS need not be hamstrung by these flawed judicial interpretations. None of those court decisions directly address administrative enforcement mechanisms and remedies. Moreover, Congress gave HHS express authority to promulgate § 1557 implementing regulations.[413] We urge HHS to clearly articulate the appropriate standard for enforcement and remediation based upon a plain reading of the statute.

Section 1557 is distinct from other ACA provisions because its language focuses on protections for individuals, rather than requirements for health care entities. To begin, § 1557 refers to four existing civil rights statutes to establish which individuals are protected:

> [A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments Act of 1972 (20 U.S.C. et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity[414].

In § 1557, Congress uses words of limitation. It does not incorporate wholesale the referenced statutes. Instead, it prohibits discrimination on the "ground prohibited under" four statutes: race, color or national origin (the grounds under Title VI of the Civil Rights Act; sex (the ground under Title IX of the Education Amendments of 1972; age (the ground under the Age Discrimination Act of 1975; and disability (the ground under § 504 of the Rehabilitation Act).

In contrast to how it established the grounds for discrimination (namely, the "grounds under" the reference statutes), § 1557 broadly applies the enforcement mechanisms that are "provided for and available under" the referenced statutes:

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[412] See, e.g., *Southeastern Penn. v. Gilead*, 102 F. Supp. 3d 688, 699 n.3 (E.D. Pa. 2015); *Briscoe v. Health Care Serv. Corp*., 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017); see also, *Doe v. BlueCross BlueShield of Tennessee, Inc*., 926 F.3d 235, 241 (6th Cir. 2019).
[413] 42 U.S.C. § 18116(c).
[414] 42 U.S.C. § 18116(a).

> The 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.[415]

The words Congress chose make it clear that individuals can avail themselves of any of the enforcement mechanisms available under the referenced statutes, not just the piecemeal application of mechanisms contained within each individually. If § 1557 were limited by the constraints of the referenced statutes, its passage would have been largely unnecessary, as the four civil rights statutes already apply to organizations "in the business of providing . . . health care." Moreover, § 1557 should be read within the context and purpose of the ACA as a whole.[416]

Congress also used specific terms— "provided for and available under" — when establishing § 1557's enforcement mechanisms. The term "provided for" means "as contained in the statutes."[417] Section 1557 then broadens the enforcement mechanisms to those "available under" the statutes, thus including the enforcement mechanisms available in regulations promulgated pursuant to the statutes.[418] Use of the word "and" between the two elements indicates both elements must be satisfied.[419]

Congress further distinguished § 1557's enforcement mechanisms and the grounds of discrimination by changing the order of the referenced statutes. Congress lists the grounds of discrimination as Title VI, Title IX, Age Discrimination Act, and § 504. In the enforcement mechanisms, it changes that order and the wording used to group the statutes: "under such title VI, title IX, section 794, or such Age Discrimination Act."[420] Had Congress intended to attach the remedies to the grounds, § 1557 could have simply said, "enforcement mechanisms attaching to the grounds available under the

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[415] *Id.*

[416] *National Federation of Independent Business v. Sebelius*, 567 U.S. 519,547 (2012) (noting in the ACA, "Congress addressed the problem of those who cannot obtain insurance coverage because of preexisting conditions or other health issues.").

[417] See William C. Burton, Burton's Legal Thesaurus 44, 527 (5th ed.) (2013).

[418] See *Kungys v. United States*, 485 U.S. 759, 778 (1988) ("It is a 'cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant.").

[419] See, *e.g*., *Pueblo of Santa Ana v. Kelly*, 932 F. Supp. 1284, 1292 (D.N. Mex. 1996).

[420] 42 U.S.C. § 18116(a).

statutes listed above." Instead, Congress rearranged and grouped together the enforcement mechanisms available under three statutes—"such" title VI, title IX, and § 794—while carving out "or such Age Discrimination Act of 1975.

This is not surprising. Unlike the other three civil rights statutes referenced in § 1557, the Age Discrimination Act is not self-implementing and requires regulations to establish and enforce its protections.[421] Accordingly, we do not object to the separate administrative procedures for age-related complaints. However, we endorse comments from our colleagues at Justice in Aging that discrimination complaints on more than one bases, and including age, should not be unduly delayed. (See also the discussion of intersectional complaints below.)

We thus appreciate HHS's recognition in the preamble of the unique and compounding harms intersectional discrimination causes older adults and others. We support clear, accessible procedures for filing, investigating, and remediating discrimination complaints, including intersectional claims. As § 1557 is its own statute enforceable by private right of action in the courts, an older adult who is discriminated against based on age **and** race, national origin, sex, and/or disability should not be at a disadvantage for seeking recourse due to the Age Act's administrative exhaustion requirements. Therefore, we recommend that HHS include regulatory language in the final rule that clarifies that administrative exhaustion is **not** required to bring an intersectional claim including age under § 1557. We urge HHS to identify other ways to address intersectional discrimination in the regulatory provisions of the rule itself, including making an explicit reference to intersectional discrimination in the regulatory text of Proposed § 92.101.

By referencing both the statutes and their regulatory frameworks, Congress established broad enforcement mechanisms, including for disparate treatment and disparate impact, for § 1557. The regulations for Title VI, for example, "extend beyond acts of intentional discrimination and reach conduct and practices that, even if facially neutral, have a disproportionate adverse impact on members of minority groups."[422]

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[421] See 42 U.S.C. § 6102.

[422] Sara Rosenbaum & Joel Teitelbaum, *Civil Rights Enforcement in the Modern Healthcare System: Reinvigorating the Role of the Federal Government in the Aftermath of Alexander v. Sandoval*, 3 YALE J. HEALTH POL'Y L. & ETHICS 215, 218 (2003) (noting that federal agencies promulgated twenty-two sets of rules implementing the Civil Rights Act); see also Sidney D.

HHS seeks comments on disparate impact discrimination, and “whether it should be limited to discrimination on the basis of sex, or should also include each of the enumerated grounds covered under § 1557’s statutory prohibition on discrimination.”[423]

By expressly including enforcement mechanisms “available under” the statutes, Congress has authorized disparate impact claims to be brought under § 1557. Section 1557 recognizes the reality that discrimination “may occur not solely because of the person’s race or not solely because of the person’s sexual orientation or gender identity, [disability status, or national origin], but because of the combination.”[424] Thus, the law aimed to make it easier for people to file complaints of intersectional discrimination in one place. Congress explicitly adopted one provision to prohibit discrimination on multiple bases in health care. It strains the imagination to read that one provision would require agencies and courts to apply a hodgepodge of standards and enforcement mechanisms. It is also necessary to read § 1557 as establishing a single standard for addressing health care discrimination to avoid “patently absurd consequences.”[425]

Section 1557 recognizes that people often experience discrimination based on more than one protected category. For example, if a Black woman experiences discrimination in seeking health care, it may be impossible to separate out only one of these identities – race or sex – as the basis of discrimination. A majority of federal courts have correctly recognized that discrimination on the basis of a combination or the interrelationship of multiple protected characteristics is actionable under federal non-discrimination laws. These courts recognize that “where two bases of discrimination exist, the two grounds cannot be neatly reduced to distinct components” because they often “do not exist in isolation.”[426]

Watson, *Reinvigorating Title VI: Defending Health Care Discrimination—It Shouldn't Be So Easy*, 58 FORDHAM L. REV. 939, 948 (1990) (listing regulations defining discrimination to encompass both intentional and disparate impact discrimination).

[423] 87 Fed. Reg. 47860.

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

[425] *United States v. Brown*, 333 U.S. 18, 27 (1948).

[426] *Shazor v. Prof’l Transit Mgmt.,* 744 F.3d 948, 957-58 (6th Cir. 2014). *See also*, e.g., *Harris v. Maricopa County Superior Court*, 631 F.3d 963, 976 (9th Cir. 2011); *Jefferies v. Harris Co.*

Congress did not intend that the enforcement mechanisms and standards available under § 1557 be tied to the nature of the claim, but instead created an enforcement mechanism tailored to allow affected individuals to address the discriminatory practices the ACA was designed to ameliorate. HHS administrative enforcement procedures and remedies should reflect this intent.

§ 92.302 Notification of views regarding application of Federal conscience and religious freedom laws

Section 1557's very purpose is to address longstanding health care discrimination, which continues to create numerous barriers to affordable, culturally and linguistically appropriate, and high-quality health services. Patients are often harmed by the imposition of federal health care refusal laws. Covered entities have long relied on health care refusal laws to discriminate against and violate medical standards of care for people who need or have used sexual or reproductive health care, LGTBQI+ people, and people with disabilities.[427]

Too often, LGBTQI+ people and women are unable to access needed health care services because covered entities invoke conscience and religious objections to refuse care.[428] For example, after a man with HIV disclosed to a hospital that he had sex with other men, the hospital staff refused to provide his HIV medication.[429] A woman's

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Community Action Ass'n, 615 F.2d 1025, 1032 (5th Cir. 1980); *Jeffers v. Thompson*, 264 F. Supp. 3d 314, 326 (D. Md. 2003).

[427] Emily London & Maggie Siddiqi, Ctr. for Am. Prog., *Religious Liberty Should Do No Harm*, Apr. 11, 2019, https://www.americanprogress.org/article/religious-liberty-no-harm.

[428] *See* Amy Chen, Nat'l Health L. Prog. Blog, *Health Care Refusals & How They Undermine Standards of Care Part II: The Impact of Health Care Refusals, Discrimination, and Mistreatment on LGBTQ Patients and Families*, Jun. 13, 2022, https://healthlaw.org/health-care-refusals-how-they-undermine-standards-of-care-part-ii-the-impact-of-health-care-refusals-discrimination-and-mistreament-on-lgbtq-patients-and-families; Sharita Gruberg et al., Ctr. Am. Prog., *The State of the LGBTQ Community in 2020* (2020), https://www.americanprogress.org/article/state-lgbtq-community-2020/.

[429] Nat'l Women's L. Ctr., *Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS* 2 (2014), https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

emergency care was delayed leading to serious complications when emergency room staff learned of her sexual orientation.[430] Similarly, a pediatrician's office refused to make an appointment for an infant because she had Lesbian parents.[431] Hospitals have refused to allow doctors with admitting privileges to provide their patients medically necessary reproductive health and gender-affirming care in their hospitals.[432] Reproductive health clinics have declined to provide assisted reproductive services to same-sex couples.[433] A 2020 survey found that a quarter of transgender respondents had been refused health care because of their gender identity.[434]

People in rural communities, people with low-incomes, and BIPOC often rely on religiously affiliated covered entities, which comprise a major part of the U.S. health care system. Women of color disproportionately give birth in Catholic hospitals and are therefore refused many facets of comprehensive sexual and reproductive health care.[435] Religiously affiliated covered entities often turn patients away during emergencies such as miscarriages without informing them about their health status or treatment options, placing their health and lives at risk.[436]

Thus, while we understand that § 1303 of the ACA incorporates federal health care refusal laws, we cannot overstate the extent to which their imposition undermines

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[430] *Id.*

[431] *See* Phillip, *supra* note 374.

[432] Movement Advancement Proj. & Nat'l Ctr. Transgender Equity, *Religious Refusals in Health Care: A Prescription for Disaster* 6, 8 (2018), https://www.lgbtmap.org/file/Healthcare-Religious-Exemptions.pdf.

[433] *Id.* at 8.

[434] *See* Gruberg, *supra* note 428.

[435] Kim Shepherd et al., *Bearing Faith: The Limits of Catholic Health Care for Women of Color* (2018), https://lawrightsreligion.law.columbia.edu/bearingfaith.

[436] See e.g., Julia Kaye et al., ACLU,, *Health Care Denied* (2016), https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied (includes the story of Tamesha Means, who was turned away from a Catholic hospital—the only hospital in her community—in the midst of a painful, nonviable miscarriage); *Below the Radar: Health Care Providers' Religious Refusals Can Endanger Pregnant Women's Lives and Health*, NAT'L WOMEN'S L. CNTR., Jan. 2011, https://nwlc.org/wp-content/uploads/2015/08/nwlcbelowtheradar2011.pdf (includes the stories of two women who were refused the full spectrum of appropriate care for an ectopic pregnancy at their local emergency rooms).

§ 1557's statutory charge to prohibit discrimination in health care. Given the severe harms of health care refusals to sexual, reproductive, and broader health care access, we strongly agree that there should be no blanket exemptions from § 1557 for religious or other entities. Accordingly, we support HHS's proposal to establish procedures whereby recipients may submit exemption requests to OCR, which will then engage in a "fact-sensitive, case-by-case analysis" to determine whether the covered entity is entitled to an exemption.[437] Blanket exemptions based on a covered entities' asserted beliefs would not only close the door on a wide range of health services around the country, they would be inconsistent with the requirements of applicable federal care refusal laws.

For example, under the Religious Freedom Restoration Act (RFRA), if a regulation places a substantial burden on religious exercise, the government must show the regulation furthers a compelling interest using the least restrictive means. Minimal burdens do not trigger RFRA protection. Moreover, RFRA requires a careful and individualized review. When a provider files a claim under RFRA, HHS OCR is not only permitted but required to inquire into the circumstances underlying the claim. For example, OCR must ensure that the burden is "substantial;" the religious belief is sincerely held; and the requested accommodation is tailored to address the burden. The government's ability to grant exemptions under RFRA is not unlimited: under the Constitution, the government cannot grant exemptions that would materially harm others, including people seeking health services.

HHS absolutely must evaluate exemptions from § 1557 protections on a case-by-case basis, as blanket exemptions would almost certainly result in overbroad denials of § 1557's protections. However, HHS must strengthen Proposed § 92.302 by including regulatory text to ensure that OCR's inquiries into a covered entity's exemption requests do not unduly delay an individual's access to health services. HHS must also carefully weigh the ramifications of each potential exemption on the pertinent individual's health and wellbeing. This is particularly critical as the types of health services most often subject to refusals, such as sexual and reproductive health services; services for people with disabilities that may prevent, cause complications to, or end pregnancies; and treatments for emergency medical conditions are often extremely time sensitive. However, the Weldon Amendment, Church Amendments, and Coates-Snowe

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[437] 87 Fed. Reg. at 47841.

Amendment allow certain entities and individuals to deny health care without protections for people seeking care. HHS must carefully weigh covered entities' asserted rights to deny care against immediate, long-term, and potentially intergenerational harms to patients (see, *e.g.*, our discussion on how abortion barriers impact health outcomes and equity in our comments on § 92.101).

Further, we recommend that HHS clarify that this section applies to any federal law exemptions to this part, including religious exemptions. While it is not possible to lay out all the standards for exemption with exacting clarity because of the potential breadth of laws that may give rise to exemptions, HHS should make clear in the preamble to the rule that it will publish determination letters that provide 1) the requested exemption, 2) any relevant provisions of law, and 3) a legal analysis for the determination. This would provide guidance to applicants over time.

We strongly agree with HHS's conclusion that the Danforth Amendment (Danforth), Title IX's abortion neutrality provision, does not apply to § 1557, and that *Franciscan Alliance v. Burwell*, which we maintain was wrongly decided, does not bind this new rulemaking.[438] The ACA's silence on the Danforth Amendment is not an oversight, but rather an intentional omission, as "Congress legislates with knowledge of our basic rules of statutory construction."[439] While § 1557 incorporates the bases of discrimination prohibited by Title IX, Congress purposefully did not incorporate Title IX's exemptions. Thus, HHS exceeded its statutory authority when it incorporated Danforth in its Final 2020 Rule. On August 26, 2022, the Fifth Circuit confirmed that Franciscan Alliance's Administrative Procedures Act claim is moot because "Franciscan Alliance cannot use the APA to vacate [the Whitman-Walker] injunction[] or Section 1557."[440]
Moreover, the *Franciscan Alliance* decision is only one pertinent case. In fact, the court in *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs*. came to the opposite conclusion regarding the inclusion of Title IX's religious exemption, declaring it

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

[439] *McNary v. Haitian Refugee Center,* 498 U.S. 479, 496 (1991) (referring to presumption favoring judicial review of administrative action). *See also United States v. Fausto*, 484 U.S. 439, 463 n.9 (1988) (Stevens, J., dissenting) (Court presumes that "Congress is aware of this longstanding presumption [disfavoring repeals by implication] and that Congress relies on it in drafting legislation.").

[440] *Franciscan All., Inc. v. Becerra*, 2022 WL 3700044, at *4 (5th Cir. Aug. 26, 2022).

arbitrary and capricious under the APA.[441] Specifically, the court in *Whitman-Walker* found that the 2020 Final Rule's inclusion of Danforth violated the APA because the Department had failed to consider how this inclusion would impact access to care—the central purpose of § 1557 and the ACA itself.[442]

Further, as a policy matter, applying the Danforth Amendment to § 1557 will threaten the health and lives of pregnant people. It will enable covered entities to erect additional restrictions on abortions and related care. In states with gestational age bans, overcoming yet another obstacle that impacts timely abortion access could increase the rate of forced births and related maternal morbidity and mortality. Thus, HHS must repeal this provision.

Lastly, we strongly support HHS's affirmation that exemptions to federal health care refusal laws are subject to important caveats. In particular, we appreciate HHS's affirmation that EMTALA's protections for stabilizing treatment for people with emergency medical conditions may trump health care refusal laws.[443] This affirmation is particularly important as more and more states enact abortion bans and severe restrictions in the wake of *Dobbs*, and more and more covered entities deny access to stabilizing treatments such as methotrexate for ectopic pregnancy or mifepristone and misoprostol for miscarriage management. In our comments on Proposed § 92.206 and § 92.207, we urge HHS to enumerate related forms of discrimination in the regulatory text.

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[441] *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs*., 485 F. Supp. 3d 1, 43-46 (D.D.C. 2020).

[442] *Id*. at 44-45.

[443] *See, e.g.*, Letter from Xavier Becerra, *supra* note 176.

§ 92.303 Procedures for health programs and activities conducted by recipients and State Exchanges
and
§ 92.304 Procedures for health programs and activities administered by the Department

A. Remedies

We support restoring the administrative procedures under the 2016 Final Rule. However, we suggest HHS merge proposed § 92.303 and § 92.304. Combining these two regulatory provisions would help reduce confusion among complainants. HHS should further clarify that HHS OCR is the lead administrative enforcement entity for § 1557.

We recognize that administrative enforcement procedures and remedies may differ according to the type of covered entity. For example, recipients of FFA, including State-based Marketplaces, may face a reduction or loss of federal funding for non-compliance, so the opportunity for a hearing would be appropriate; whereas enforcement actions against the Department would not require a hearing.

As the 2022 Proposed Rule acknowledges, gaps exist in the Title VI and Section 504 procedures, including protections against retaliation and requirements for documents. We support HHS's proposal to fill in those gaps. However, the § 504 compliance procedures, applicable to the Department, expressly include a provision that if HHS OCR does not have jurisdiction over a complaint, it will refer it to the appropriate office or agency.[444] We note there is no corresponding provision in the Title VI procedures, applicable to recipients of FFA. We recommend that HHS include such a provision in § 92.303.

We also note that 45 C.F.R. § 80.6(b), which governs Title VI compliance and enforcement, requires recipients to gather some data on the race and ethnicity of program participants. Section 1557 data collection should be broader (see discussion on § 92.5).

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[444] *See* 45 C.F.R. § 85.61(e).

We also suggest that this section (or sections if our recommendations are not accepted) would be logical place to reinforce procedures for intersectional claims. We recommend adding specific language in the regulatory text to accompany the discussion of intersectionality throughout the Preamble. Bringing a recognition of intersectionality into the regulatory text will highlight its importance and reinforce the need to understand and address intersectional discrimination.

RECOMMENDATIONS:

1. Merge § 92.303 and § 92.304.
2. In revised § 92.303, amend (a) to add “or a combination thereof” as follows:

   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 ***or a combination thereof*** under Section 1557 or this part.

B. OCR Enforcement Actions

In addition, the final rule should include a provision that requires the publication of OCR enforcement actions, including the rationale and results of such actions, as well as the compliance correction plans. Published precedent (even if redacted to eliminate specific names) is essential for educating the health insurance industry on what conduct is and is not acceptable under § 1557. Understanding the rationale for OCR’s opinions is helpful to other covered entities in ensuring that they are compliant and helpful for consumers to understand what conduct is acceptable. Without such precedent, covered entities are left only with limited guidance, such as Frequently Asked Questions (FAQs), which, while helpful, are often not sufficiently specific to help covered entities tailor their behavior in accordance with the law.

Further, in addition to publishing resolved complaints, we recommend that HHS publish a yearly tally of the number of complaints filed disaggregated by the bases for the complaints (*e.g*. race, color, national origin, sex, disability, age, or combinations thereof), the number of investigations initiated, the number of complaints resolved, the number of complaints closed without resolution.

RECOMMENDATION: Add new § 92.304 as follows:

> ***§ 92.304 Publication of Complaints and Resolution Agreements.***
> ***(a) On at least a yearly basis, OCR shall report the following information:***
>
> > ***(i) number of complaints filed, disaggregated by the basis of the complaint;***
> > ***(ii) number of investigations initiated;***
> > ***(iii)number of complaints resolved;***
> > ***(iv)number of complaints closed without resolution; and***
>
> ***(b) Within fourteen calendar days of resolving a complaint, OCR shall publicly post on its website a narrative discussion of the resolution and the full document containing the resolution agreement.***

We also are concerned about mandatory arbitration agreements. Insurers or health care providers could include them in their contracts in an attempt to prevent beneficiaries from using the administrative and judicial remedies included in § 1557. Binding arbitration greatly favors defendants, particularly when they are large, powerful corporations. In many cases, the arbitrators have an incentive to rule in favor of the defendants, who hired them and will only hire them in the future if they are pleased with the outcome. Allowing insurance companies to restrict beneficiaries to binding arbitration for discrimination claims would subvert the intent of § 1557. We recommend that HHS include a specific provision prohibiting insurers from requiring binding arbitration as the exclusive means to resolve a complaint arising under § 1557.

OTHER PROVISIONS

Regulatory Provisions affecting other programs (Medicaid, CHIP, PACE, etc.)

We support HHS's proposal to restore language to § 1557 implementing regulations governing other programs (e.g., Medicaid, CHIP, and PACE) to clarify that prohibited sex discrimination includes sexual orientation and gender identity. These protections are crucial to protecting participants in those programs from sex discrimination.[445]

In addition, we urge HHS to align how it defines sex discrimination in these provisions and Proposed § 92.101(a)(2). Specifically, it must clarify that prohibited sex discrimination includes discrimination based on sex stereotypes, sex characteristics, including intersex traits, and pregnancy or related conditions, including termination of pregnancy. Earlier this year, we commented on the importance of such clarifications for Exchanges, QHPs, and certain issuers in response to the HHS Notice of Benefit and Payment Parameters for 2023.[446] While the non-discrimination protections for these programs have statutory bases in addition to § 1557, there is no reason to define sex discrimination differently for these programs. Rather, to ensure consistency, HHS should use the same definition in these programs as it uses for its overarching § 1557 implementing regulations.

Amending these regulations to ensure that they are consistent with § 1557's prohibitions on sex discrimination is squarely within HHS's authority. For example, SSA §§ 1902(a)(4), 2101(a), 1894(f) and 1934(f) confer "broad authority" on the Secretary of HHS to impose requirements on state Medicaid programs, CHIPs, and PACEs as

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[445] *See, e.g.*, *Fain v. Crouch,* No. CV 3:20-0740, 2022 WL 3051015 (S.D.W. Va. Aug. 2, 2022) (discrimination against transgender Medicaid beneficiaries on the basis of sex); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001 (W.D. Wis. 2019) (same); Kellen E. Baker, Ctr. Am. Prog., *The Medicaid Program and LGBT Communities* 6 (2016) (until 2015 "many Medicaid programs did not consider same-sex spouses legally married for purposes of eligibility and enrollment"), https://americanprogress.org/wp-content/uploads/2016/08/2LGBTMedicaidExpansion-brief.pdf.

[446] *See* Mara Youdelman et al., Nat'l Health Law Prog., *NHeLP Comments on 2023 Notice of Benefit and Payment Parameters Proposed Rule* 2-9 (2022), https://healthlaw.org/resource/nhelp-comments-on-2023-notice-of-benefit-and-payment-parameters-proposed-rule/.

necessary to further the administration of those programs. [447] Further, as HHS has noted, the Medicaid Act requires it to ensure that it implements safeguards necessary to ensure that the program is administered consistent with the best interests of Medicaid beneficiaries.[448]

Protecting against all forms of sex discrimination is crucially important in Medicaid, CHIP, and PACE. As detailed above, discrimination based on sex stereotypes, sex characteristics (including intersex traits), and pregnancy or related conditions, including termination of pregnancy, undermine access to care and health equity for beneficiaries, especially those who are Gender Diverse, Intersex, women, pregnant or capable of pregnancy, or people with disabilities.[449] Ensuring that these provisions are consistent with HHS's interpretation of § 1557 will improve efficiency and clarity across health care programs.

These provisions are also critically important as these programs are vital sources of coverage and care for low-income older adults who are dually eligible for Medicare and Medicaid, including LGBTQ+ older adults. Therefore, it is critical to ensure these programs, including managed care plans, are subject to strong and consistent nondiscrimination rules. To provide greater clarity for compliance and enforcement, we urge HHS to harmonize the regulatory protections in these programs with the inclusive language proposed in Proposed § 92.101(b).

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[447] *Mission Hosp. Reg'l Med. Ctr. v. Shewry*, 168 Cal. App. 4th 460, 485 (2008) (quoting *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981)); *see also Harris v. James,* 896 F. Supp. 1120, 1128 (M.D. Ala. 1995), *rev'd on other grounds,* 127 F.3d 993 (11th Cir. 1997).

[448] Social Security Act § 1902(a)(19).

[449] *See, e.g.*, MACPAC, *Access in Brief: Experiences of Lesbian, Gay, Bisexual, and Transgender Medicaid Beneficiaries with Accessing Medical and Behavioral Health Care* 1 (2022), https://www.macpac.gov/wp-content/uploads/2022/06/Access-in-Brief-Experiences-in-Lesbian-Gay-Bisexual-and-Transgender-Medicaid-Beneficiaries-with-Accessing-Medical-and-Behavioral-Health-Care.pdf; Caroline Medina & Lindsay Mahowald, Ctr. Am. Prog., *Key Issues Facing People With Intersex Traits* (Oct. 26, 2021), https://www.americanprogress.org/article/key-issues-facing-people-intersex-traits; Wing Yee Wong et al., *Improving Competency in the Care of the Older Transgender Patient: A Case Study*, 26 AM. J. GERIATRIC PSYCH. S155, S156 (2018); Sakala et al., *supra* 286.

OTHER ISSUES

Demographic Data Collection

We appreciate that HHS acknowledges the importance of demographic data collection to achieving health equity.[450] Without demographic information on individuals served through its programs and activities, HHS often fails to effectively understand program populations and ensure equity. Although HHS considered a demographic data collection requirement outside of the § 1557 regulations, we encourage HHS to adopt a basic demographic data requirement in the final rule. HHS acknowledges that demographic data currently goes largely uncollected within its programs.[451] A clear requirement would further demographic data collection across the agency, improve civil rights enforcement, and reach toward the goal of health equity.

HHS must invest in demographic data collection in any program or activity that serves the public. Only by understanding who uses each program can HHS ensure that groups of people with different experiences –and particularly members of historically underserved populations – are served equitably. Having data on hand is also the most essential and straightforward way to ensure and demonstrate compliance with § 1557's civil rights requirements. HHS writes in the 2022 Proposed Rule that data on COVID-19 treatment and outcomes disaggregated by race and ethnicity brought to light stark disparities faced by Black, Indigenous, and other People of Color (BIPOC) during the

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[450] HHS has incorporated demographic data collection into its 2022 Equity Action Plan, U.S. Dep't of Health & Hum. Svcs., *Equity Action Plan* (Apr. 2022), *available at* https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf, and demographic data collection has long been a stated priority for its subagencies; *see, e.g.*, Ctrs. for Medicare & Medicaid Svcs., *The CMS Equity Plan for Improving Quality in Medicare* (Sept. 2015), *available at* https://www.cms.gov/about-cms/agency-information/omh/omh_dwnld-cms_equityplanformedicare_090615.pdf; Ctrs. for Medicare & Medicaid Svcs., *CMS Framework for Health Equity 2022-2032* (Apr. 2022); *available at* https://www.cms.gov/files/document/cms-framework-health-equity.pdf; Ctrs. for Medicare & Medicaid Svcs., *CMS Strategic Plan, Pillar: Health Equity* (Aug. 2022), *available at* https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.

[451] 87 Fed. Reg. 47856.

COVID-19 pandemic.[452] Even more importantly, accessing this data lead to interventions to redress these disparities.[453] Yet, health data stratified by race and ethnicity remains incomplete or inadequate for subgroups, as well as for demographic categories beyond race and ethnicity. Little federal- or state-collected data is available to track such disparities among the LGBTQI+ or disability communities,[454] despite overwhelming evidence that LGBTQI+ and people with disabilities historically face health barriers at higher rates than non-LGBTQI+ and people without disabilities.[455]

States and programs that have adopted demographic data collection requirements demonstrate the feasibility of demographic data collection in health programs. Colorado recently adopted a requirement for health departments to collect patient health data on race, ethnicity, disability, sexual orientation and gender identity.[456] Oregon enacted a law in 2021 that requires insurers and health care providers to collect information on patients' race, ethnicity, preferred spoken and written language, sexual orientation, gender identity, and disability status.[457] The Medicare program recently added race and ethnicity questions to its Part C and D Enrollment Form and will test for nonresponses to

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[452] *Id*.

[453] *See, e.g*., U.S. Dep't of Health & Hum. Srvs., *HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic* Minorities (2020), *available at* https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf.

[454] *See* Nat'l Acad. of Sciences, Engineering & Medicine, *Understanding the Well-Being of LGBTQI+ Populations* 75-81 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), *available at* https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf *and* Bonnelin Swenor, *A Need for Disability Data Justice*, HEALTH AFF. (Aug. 22, 2022), *available at* https://www.healthaffairs.org/content/forefront/need-disability-data-justice.

[455] Nat'l Acad. of Sciences, Engineering & Medicine, *Understanding the Well-Being of LGBTQI+ Populations* 289 (White, J., Sepulveda M.J., & Patterson C.J., eds., 2020), https://www.ncbi.nlm.nih.gov/books/NBK563325/pdf/Bookshelf_NBK563325.pdf; Ofc. of Disease Prevention & Health Promotion, *Healthy People 2030: People with Disabilities*, https://health.gov/healthypeople/objectives-and-data/browse-objectives/people-disabilities (last visited Sept. 12, 2022).

[456] H.B. 22-1157 (Co. 2022), https://leg.colorado.gov/sites/default/files/2022a_1157_signed.pdf.

[457] H.B. 3159 (Or. 2021), *available at* https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3159/Enrolled.

these questions to better inform data collection efforts.[458] Medicare will also begin collecting information on sexual orientation and gender identity on the Medicare Current Beneficiary Survey in 2023.[459] Studies have overwhelmingly shown high acceptability among patients and enrollees in self-reporting race and ethnicity,[460] sexual orientation and gender identity,[461] and other demographic information, given that appropriate steps are taken to support data collection activities.[462] Information obtained through these data collections have shaped policy to address disparities and increase access to health care for underserved groups.[463] This information is also critical to ensure that communication, accessibility and language needs can be met on an individual basis in line with the requirements of Title VI, the Rehabilitation Act, and § 1557.

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[458] Ctrs. for Medicare & Medicaid Svcs., *Medicare Managed Care Eligibility and Enrollment*, CMS.gov (Jul. 19, 2021), https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol.

[459] 87 Fed. Reg. 19517 (Apr. 4, 2022).

[460] David Baker et al., *Patients' attitudes toward health care providers collecting information about their race and ethnicity*, 20 J. GEN. INTERN. MED. 895-900 (2005), *available at* https://pubmed.ncbi.nlm.nih.gov/16191134/; David W. Baker, et al., *Attitudes Toward Health Care Providers, Collecting Information About Patients' Race, Ethnicity, and Language*, 45 MED. CARE 1034 (Nov. 2007).

[461] Sean Cahill et al., *Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers*, PLOS ONE (2014), *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104.

[462] *See, e.g.*, Chris Grasso et al., *Planning and implementing sexual orientation and gender identity data collection in electronic health records*, 26 J. AM. MED. INFORM. ASSOC. 66-70 (2019), *available at* https://pubmed.ncbi.nlm.nih.gov/30445621/; Pittman et al., *Who, When, and How: The Current State of Race, Ethnicity, and Primary Language Data Collection in Hospitals*, The Commonwealth Fund (2004), *available at* https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2004_may_who__when__and_how__the_current_state_of_race__ethnicity__and_primary_language_data_collection_in_ho_hasnain_wynia_whowhenhow_726_pdf.pdf.

[463] *See* The Colorado Trust, *Health Equity and Race and Ethnicity Data* 10 (Sept. 2013), *available at* https://www.coloradotrust.org/wp-content/uploads/2015/03/CT_Race_EthnicityBrief_vFinal2.pdf (giving examples of interventions undertaken as a result of health disparity data).

HHS has expressed concern that codifying a demographic data collection requirement in the § 1557 regulations leaves little room for flexibility.[464] Concerns about dynamic and responsive data collection methods and standards are well-founded, given the fluctuating nature of populations and the fluid understanding of identity. However, the Department's proposed solution, which is similar to that of the Education Department (DoE), may not be the most effective approach. While we agree that HHS has the authority to require data collection and reporting for compliance reporting under § 1557 as well as other civil rights statutes, a subregulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS.[465] Establishing a requirement within the 2022 Final Rule would bring weight and clarity to demographic data collection as a key component of civil rights enforcement.

In addition, DoE's civil rights data collection program is not a good proxy for how demographic data collection within HHS could work. The scope of demographic data to be collected is much larger within HHS than within DoE; where DoE collects information from school districts and juvenile facilities, HHS must collect information from state exchanges, state Medicaid programs, hospitals, health centers, health clinics, clinicians' offices, private partners, and more. Each entity engages with patients, enrollees, and grantees by different methods and at different frequencies. This poses significant challenges when attempting to standardize and coordinate demographic data collection and reporting across the agency's many programs and activities. We believe a better approach would be to set baseline requirements within the 2022 Final Rule, but to direct each subagency or program to set its own requirements and methods for data collection with a specific timeline for implementation.

As discussed further in our comments applying § 1557 (as well as Title VI, Title IX, § 504 and the Age Act) to Medicare Part B, the historical exclusion of Medicare Part B providers from civil rights enforcement also created an exemption from data collection. As noted in a 2005 *Health Affairs* article:

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[464] 87 Fed. Reg. 47857.

[465] See Charly Gilfoil, Nat'l Health L. Prog., *Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data* (Sept. 7, 2022), *available at* https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/.

> Perhaps a more troubling and longer-term consequence of [the Part B] exemption was that no federal effort was ever mounted to collect data and monitor the extent of discriminatory medical treatment. No federal testing program was developed similar to those developed to monitor discrimination in housing and employment. No public reporting requirements have been imposed as have been on lenders for home mortgage applications and approval rates by race as a result of the Home Mortgage Disclosure Act of 1975. Yet, despite repeated calls for such data and the overwhelming role that federal dollars play in financing medical services, the void persists. There has never been a lack of regulatory authority to require such collection and reporting; it has always been a lack of political will.[466] (citations omitted)

As a specific recommendation for inclusion in the 2022 Final Rule, we recommend HHS include a general data collection requirement in § 92.5 (or create a separate regulatory section governing data collection).

Collection of demographic data is also important for planning purposes, particularly with regards to people with disabilities and limited English proficiency. Therefore, health plans and providers should be collecting disability status information, voluntarily provided by patients, as a core demographic data element. For example, collecting functional limitation information will help providers to identify patients' need for accommodations during clinical visits and hospitalizations, hopefully increasing the likelihood that accommodations needed for equally effective healthcare will be provided in a timely and consistent way. Collecting language data of individuals (and their parents and guardians for those who are minors or incapacitated) will help ensure covered entities have effective language access policies and procedures in place to meet their needs.

Frontline staff cannot be expected to process effectively detailed clinical information, across a wide variety of backgrounds, disabilities and chronic health conditions, to ensure that individuals receive appropriate language/communication services and are accommodated and receive effective care. Therefore, covered entities involved in healthcare delivery should invite individuals, at registration and when scheduling

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[466] David Barton Smith, *Racial And Ethnic Health Disparities And The Unfinished Civil Rights Agenda,* HEALTH AFF., 24, no.2 (2005):317-324.

appointments, to self-identify any language/communication issues and functional limitations and their answers should be recorded. Those who self-identify functional limitations should also be provided an opportunity to specify any needed accommodations and that information should also be added to records for future needs.

Whether HHS includes a demographic data collection requirement in the 2022 Final Rule, engages in further rulemaking, or issues subregulatory guidance, we offer the following recommendations for principles to guide demographic data collection within the agency:

- ***Develop resources and toolkits for collecting demographic data, including explaining why this data is being collected.*** The Health Research and Educational Trust (HRET) developed a toolkit for collecting race, ethnicity and language data at hospital admissions after testing different rationales for collecting this data.[467] Additional research, including case studies of data collection implementation, informs strategies and best practices for collecting data across all demographic categories.[468] HHS should review recommendations and study case to develop recommendations, toolkits, and technical assistance for programs to engage in demographic data collection in different situations (e.g. on applications, by insurers, during admissions at covered entities, during healthcare encounters).

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[467] *See* Am. Hospital Assoc., *AHA Disparities Toolkit*, *available at* http://www.hretdisparities.org (last visited Sept. 12, 2022).

[468] *See* Ruben D. Vega Perez et al., *Improving Patient Race and Ethnicity Data Capture to Address Health Disparities: A Case Study from a Large Urban Health System*, 14 CUREUS 1 (2022) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8815799/; Colin Planalp, State Health Access Data Assistance Ctr. (SHADAC), *New York State of Health Pilot Yields Increased Race and Ethnicity Question Response Rates*, State Health & Value Strategies (Sept. 9, 2021), https://www.shvs.org/new-york-state-of-health-pilot-yields-increased-race-and-ethnicity-question-response-rates/; Elizabeth Lunkanen and Emily Zylla*, Exploring Strategies to Fill Gaps in Medicaid Race, Ethnicity, and Language Data*, State Health Access Data Assistance Ctr. (SHADAC) (2020), https://www.shvs.org/exploring-strategies-to-fill-gaps-in-medicaid-race-ethnicity-and-language-data/.

- ***Adopt clear privacy and nondiscrimination protections.*** For a data collection requirement to be impactful, individuals must feel comfortable disclosing personal information that can help to improve the care they receive and foster a broader understanding of health care disparities. We encourage HHS to clarify that the privacy protections in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 as well as other federal and state law apply to demographic data . HHS should ensure that individuals are made aware of their privacy protections and rights, the reason this information is being collected, and who will have access to what forms of information.

- ***Safeguard that reporting of demographic data be voluntary.*** While covered entities should be required to ask for demographic information (and for minors or incapacitated individuals, the spoken/written language, communication, and accessibility needs of their parents/guardians), the responses to data collection requests are (and should be) voluntary to report and should be self-reported to ensure accuracy.

- ***Set, review, and update minimum standardized variables for each demographic category.*** Since 1977, OMB has instructed federal agencies to use specific variables when collecting information about race and ethnicity. In 2011, HHS set minimum standards for collecting data about race, ethnicity, sex, language, and disability (the 2011 Data Standards).[469] However, these requirements were limited to data collected from surveys only. HHS must set minimum variables for data collection across **all** of its programs and agencies, whether for survey data, administrative data, or clinical data. We offer the following recommendations for minimum variables in each demographic category:

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[469] U.S. Dep't of Health & Hum. Srvs., *Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status* 8 (Oct. 30, 2011), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//43681/index.pdf.

- ***Race and Ethnicity*.** HHS should adopt the race and ethnicity variables used in the 2011 Data Standards.[470] HHS should make recommendations on ways to further disaggregate Latinx, Asian, and Native subgroups and add variables to reflect the Middle Eastern and North African (MENA) community.[471]

- ***Primary Language***. HHS should require programs to collect information about the spoken and written language used by each individual served.

- ***Disability Status***. HHS should adopt the disability status data collection methods found in the 2011 Data Standards. This six-question format, also used on the American Community Survey captures information on a range of disabilities, including whether an individual is Deaf or hard of hearing, is blind or low-vision, or has a physical, functional, mental, or emotional disability. We also recommend that HHS review and add data collection methods that capture information about an individual's communication abilities, psychological and learning disabilities, and autism.

- ***Sex Characteristics***. HHS should adopt the recommendations of the NASEM Committee in its 2022 report, *Measuring Sex, Gender Identity, and Sexual Orientation*.[472] Few surveys collect information on individuals

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[470] The Office of Management and Budget is currently in the process of updating Directive No. 15, which sets minimum standards for federal agencies to use when collecting information about race and ethnicity. See Karin Orvis, *Reviewing and Revising Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity*, THE WHITE HOUSE: BRIEFING ROOM BLOG (Jun. 15, 2022), https://www.whitehouse.gov/omb/briefing-room/2022/06/15/reviewing-and-revising-standards-for-maintaining-collecting-and-presenting-federal-data-on-race-and-ethnicity/. Per 42 U.S.C. § 300kk, HHS is required to update its race and ethnicity data collection standards to align with the race and ethnicity standards given by OMB, at a minimum.

[471] *See* Victor Rubin et al., PolicyLink, *Counting a Diverse Nation: Disaggregating Data on Race and Ethnicity to Advance a Culture of Health* 24-26 (2018), *available at* https://www.policylink.org/sites/default/files/Counting_a_Diverse_Nation_08_15_18.pdf.

[472] Nat'l Academies of Sciences, Engineering, & Medicine, *Measuring Sex, Gender Identity, and Sexual Orientation* (Nancy Bates, et al., eds., 2022), *available at* https://nap.nationalacademies.org/catalog/26424/measuring-sex-gender-identity-and-sexual-orientation.

with differences in sex characteristics or intersex traits. Yet, the occurrence of individuals who have non-normative sex traits, such as differences in hormones or anatomy, is significant considering the number of individuals who may be intersex, who have had gender-affirming treatment, or who may have other medical conditions (such as a mastectomy for the purpose of treating breast cancer). An anatomical or organ inventory provides greater utility both medically and demographically when it comes to identifying sex traits.[473] HHS should test methods of collecting demographic information about sex characteristics that can be used widely.

- ***Gender Identity and Sex***. HHS should adopt the recommendations of the NASEM Committee in its 2022 report, *Measuring Sex, Gender Identity, and Sexual Orientation*. The Committee recommends collecting two data points – the sex classification on an individual's original birth certificate and the individual's current gender identity – to identify both the individual's gender and whether or not the individual is transgender. The Committee notes the low nonresponse rate – less than 1% for both sex and gender identity data points – which is consistent with past studies on gender identity data collection.[474] As discussed above, sex classification is less useful than an organ inventory for identifying an individual's specific anatomy. However, in the context of gender identity, collecting information about an individual's sex classification at birth is the most reliable proxy to identify transgender individuals currently known.

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[473] Chris Grasso et al., *Optimizing gender-affirming medical care through anatomical inventories, clinical decision support, and population health records in electronic health record systems*, 28 J. AM. MED. INFORM. ASSOC. 2531-35 (Oct. 2021), https://pubmed.ncbi.nlm.nih.gov/34151934/.

[474] Nat'l Academies of Sciences, Engineering, & Medicine, *Measuring Sex, Gender Identity, and Sexual Orientation* 55, 80 (Nancy Bates, et al., eds., 2022), https://nap.nationalacademies.org/catalog/26424/measuring-sex-gender-identity-and-sexual-orientation; Sean Cahill et al., *Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers*, PLOS ONE (2014), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104.

  - ***Sexual Orientation***. HHS should adopt the recommendations of the NASEM Committee in its 2022 report *Measuring Sex, Gender Identity, and Sexual Orientation*.

- ***Support analyses based on multiple demographic variables.*** While we recommend several specific demographic variables for data collection to better ensure civil rights compliance, it should be emphasized that these variables are neither mutually exclusive nor unrelated. As individuals, each person has a sex, race, ethnicity, primary language, and disability status, and all these demographic identities interact in relevant ways for understanding and addressing health disparities. At the community and population level, these variables, both individually and in combination, can be explanatory for discrimination. For example, racial and ethnic minority women receive poorer quality care than racial and ethnic minority men, who receive poorer care than white men.[475] Spanish-speaking Latinx individuals experience poorer quality care than English-speaking Latinx individuals, who experience poorer care than non-Latinx whites.[476] Compared to women without disabilities, women with disabilities are more likely not to have regular mammograms or Pap tests.[477] Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive technology.[478] While discrimination investigation sometimes focuses on variations based on a single demographic variable, it is

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[475] Correa de Araujo R. et al., *Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarction and heart failure associated co-morbidities*, 16 WOMEN'S HEALTH ISSUES 44-56 (2006); Chou A.F. et al., *Gender and racial disparities in the management of diabetes mellitus among Medicare patients*, 17 WOMEN'S HEALTH ISSUES 150-61 (2007).

[476] Cheng E.M., Chen A., and Cunningham W., *Primary language and receipt of recommended health care among Hispanics in the United States*, 22 J. GEN. INTERN. MED. 283-88 (2007); DuBard C.A. and Gizlice Z., *Language spoken and differences in health status, access to care and receipt of preventive services among U.S. Hispanics*, 98 AM. J. PUB. HEALTH 2021-28 (2008).

[477] Diab, M.E. and M.V. Johnston, *Relationships between level of disability and receipt of preventive health services*, 85 ARCHIVES OF PHYSICAL MEDICINE & REHABILITATION 749-757 (2004).

[478] Mandell D.S. et al., *Racial/ethnic disparities in the identification of children with autism spectrum disorders*, 99 AM. J. PUB. HEALTH 493-98 (2009); Kaye H.S., Yeager P., and Reed M., *Disparities in usage of assistive technology among people with disabilities*, 20 ASSIST. TECHNOL. 194-203 (2008).

vital that HHS's civil rights enforcement support an intersectional analyses based on multiple demographic variables. This requires standardized categories and definitions for all these demographic variables.

- ***Conduct Regular Review and Engage Community Feedback***. Distinct communities are experts on their own data and should be centered in any approach to engage in widespread data collection. Input from members of diverse groups generates higher participation and response rates, ensures that terminology used is culturally appropriate, and improves transparency and accountability.[479] We support the use of focus groups, listening sessions, and direct outreach for testing of data collection methods and community feedback to revise the data collection standards adopted. We encourage HHS to look for ways to incorporate regular stakeholder feedback, such as community advisory boards, in its data collection efforts. Regular review of responses and community input can ensure that response options are valid and representative of the general population.

- ***Ensure Public Reporting of Data and Analysis***. For meaningful accountability, HHS must make the resulting data available and accessible by the public and by researchers. Delays and barriers result in less accountability and less public ownership and agency over data.

RECOMMENDATION: Add new section (d) to § 92.5 Assurances:

(d) Data Collection.

(i) Applicability. A covered entity shall, as a condition of receipt of such funds, collect demographic data of all the individuals served.

(ii) Standards. An entity described in paragraph (i) must:

(A) collect this data in a form and manner determined by the Secretary, but which at minimum shall include demographic categories for race, ethnicity, spoken and written language,

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[479] Stella S. Yi et al., *The Mutually Reinforcing Cycle of Poor Data Quality and Racialized Stereotypes that Shapes Asian American Health*, HEALTH AFF. (Feb. 2022), *available at* https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01417; Karen Wang, Theresa Cullen, and Marcella Nunez-Smith, *Centering Equity in the Design and Use of Health Information Systems: Partnering with Communities on Race, Ethnicity, and Language Data*, HEALTH AFF. (2019), https://www.healthaffairs.org/do/10.1377/forefront.20210514.126700/.

disability status, age, sex and gender identity, sex characteristics, and sexual orientation;

- ***(B) provide this data to HHS at intervals determined by the Secretary and in a manner determined by the Secretary, to document compliance with this Part; and***
- ***(C) comply with relevant privacy protections in federal and state law, including HIPAA, when collecting, storing, sharing, and otherwise using this data.***

Discrimination based on Race and Ethnicity

While the Proposed Rule does not have specific provisions related to discrimination based on race and color, we do want to emphasize the importance of protecting individuals from this discrimination and the compounding impact race and color can have on intersectional discrimination. Discriminatory health care systems and policies play an outsized role in the ability of people of color to access quality health care in the United States. Given the deep legacy of racism and other forms of discrimination in health systems and health policy, § 1557 of the Affordable Care Act is a significant step towards rectifying centuries of policies and practices that have created worse health outcomes for underserved groups.

This 2022 Proposed Rule not only clarifies the broad civil rights protections extended in § 1557, but provides concrete tools to combat racism and other forms of discrimination in health care. First, the 2022 Proposed Rule addresses various forms of discrimination that disproportionately affect communities of color, including on the basis of disability status, age, national origin, and sex. Second, the 2022 Proposed Rule addresses systemic discrimination, including policies and practices that harm people of color. Ultimately, we support this Proposed Rule as an important regulatory effort to address discrimination and racism in health care.

Federal law has prohibited race discrimination in health care since the passage of Title VI of the Civil Rights Act of 1964. However, Title VI does not apply to all health care-related activities and programs, nor does it apply to all forms of discrimination in health care. Section 1557 therefore fills in a critical gap by extending anti-discrimination protections to patients at the intersection of multiple identities. The 2022 Proposed Rule proscribes many forms of discrimination that amplify the impacts of racism and subject people to dual discrimination. For example, the 2022 Proposed Rule seeks to eliminate discrimination against LEP individuals and people living with disabilities—groups that are predominately comprised of people of color. Both cisgender women of color and LGBTQI+ people of color face racism in health care that is amplified by their gender, sexual orientation, or gender identity.

It has been long recognized that the denial of adequate language services to LEP individuals constitutes discrimination on the basis of national origin. However, there are clear intersections between LEP status and race and/or ethnicity. According to the most recent data, 63% of LEP individuals are Latinx and 21% are Asian/Pacific Islander.[480] Moreover, according to one study, a "substantial number of Asian Americans reported encountering racial discrimination and possessing limited English proficiency."[481] Another study revealed that "more than half (65%) of [patients in the study] indicated that they have felt discriminated against by [health care] staff because of their Hispanic ethnicity or LEP."[482] Improving language access services is therefore a critical tool to addressing discrimination against people of color by health care providers.

Improving health care access for people living with disabilities is critical to reducing racial health disparities. Black people are more likely to have a disability relative to White people in every age group, and according to the National Disability Institute, 14% of Black people live with disabilities compared to 11% of Non-Hispanic Whites and 8% of Latinos.[483]

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[480] MPI, *The Limited English Proficient Population in the United States in 2013* (July 8, 2015), https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013.

[481] Gilbert C. Gee and Ninez Ponce, *Associations Between Racial Discrimination, Limited English Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California*, AM. JOURNAL OF PUBLIC HEALTH Vol. 100, No. 5 (May 2010), https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2009.178012.

[482] William A. Calo et al., *Experiences of Latinos with limited English proficiency with patient registration systems and their interactions with clinic front office staff: an exploratory study to inform community-based translational research in North Carolina,* BMC HEALTH SERVICES RESEARCH 15, 570 (2015), https://doi.org/10.1186/s12913-015-1235-z.

[483] Nanette Goodman, et al., National Disability Institute, *Financial Inequality: Disability, Race and Poverty in America*, https://www.nationaldisabilityinstitute.org/wp-content/uploads/2019/02/disability-race-poverty-in-america.pdf.

The 2022 Proposed Rule clarifies discrimination on the basis of sex as including, but not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. Proscribing discrimination on these bases will improve health care access for LGBTQI+ people of color, in particular. Further, transgender people of color face significant barriers to health care access. As noted in a recent report by the Centers for American Progress, transgender people of color more frequently experience denial of care and medical abuse than white transgender people.[484] That report further notes that transphobia is often inseparable from racism and sexism in the medical system. Moreover, 65 percent of transgender people of color report experiencing some form of discrimination, and 46 percent of transgender people report having their health insurance deny gender affirming care.[485] Furthermore, some transgender people report experiencing such hostile discrimination that doctors have refused to treat conditions such as asthma or diabetes.[486]

OCR properly notes that racial health disparities in the United States are directly attributable to "persistent bias and racism" in the health care system. Both intentional and unintentional race discrimination serve as barriers to care, lead to lower quality care, and drive worse health outcomes for communities of color. Discrimination in health care is often systemic—deeply embedded within the policies, procedures, and practices of covered entities.

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[484] Caroline Medina et al., Ctr. for Am. Progress, *Protecting and Advancing Health Care for Transgender Adult Communities,* (Aug. 18, 2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/.

[485] Ctr. for Am. Progress, *Press Release: New Data and Analysis Illustrate Disparities in Health Status and Access to Care for Transgender Adults* (Aug. 18, 2021), https://www.americanprogress.org/press/release-new-data-analysis-illustrate-disparities-health-status-access-care-transgender-adults/.

[486] Medina et al.*, supra note* 484*.*

Accessible Medical and Diagnostic Equipment

We appreciate OCR's invitation to comment on the importance of adopting the Access Board's 2017 Medical Diagnostic Equipment Accessibility Standards into enforceable regulation.[487] We now have had almost six years to see what individual health providers and facilities, health care systems, hospitals, health insurers, and federal and state health care agencies would voluntarily do with the detailed, thorough consensus standards developed by the Access Board, and the answer is "very little." The U.S. Department of Veterans' Affairs adopted the standards soon after their completion and applies them to the agency's new equipment acquisitions but this example was not followed by others.[488] In those five years, people with mobility, developmental, and strength and balance disabilities across a range of ages, different races/ethnicity, and LGBTQ+ status have continued to be denied access to the most basic medical procedures: a physical exam and an accurate measure of weight.

Inaccessible equipment is not a matter of mere inconvenience. Even if a disabled person has a family member or friend who might be able to accompany them to an appointment and provide transfer assistance, the consequences of doing so are borne unequally by low-income individuals and families of color who are least able to afford time off. The ability to receive effective health care in one's own community, with one's freely chosen provider, in a manner that is as timely and appropriate as the care received by persons without disabilities, should not depend on whether one uses a wheelchair or has certain chronic conditions or is aging, but without enforceable medical diagnostic equipment standards this is the reality for thousands of people with disabilities.

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[487] Architectural and Transportation Barriers Compliance Board, *Standards for Accessible Medical Diagnostic Equipment* (Jan. 9, 2017), https://www.regulations.gov/document/ATBCB-2012-0003-0077.

[488] U.S. Dept. of Veterans Affairs, *Press Release: VA Adopts New Standards for Medical Diagnostic Equipment* (Apr. 20, 2017), https://content.govdelivery.com/accounts/USACCESS/bulletins/19450a9.

PART VI. EXECUTIVE ORDER 12866 AND RELATED EXECUTIVE ORDERS ON REGULATORY REVIEW

We appreciate HHS's careful consideration of options and its analysis of the potential costs for implementing the proposed rule. We agree with HHS' conclusion that the proposed rule will not have a significant impact on a substantial number of small entities. Further, we believe HHS's estimate of the expected costs and benefits appropriately balances the need for strong implementation and enforcement of § 1557 but not imposing significant new costs or time requirements on covered entities. The benefits identified by HHS include health improvements as well as regulatory clarity. We further agree with HHS's conclusions that the alternatives considered did not strike the appropriate balance needed and thus support the conclusions HHS drew in evaluating available alternatives.

PART VII. REQUEST FOR COMMENT

We appreciate HHS's request for comment on specific issues contained in this part. We have provided comments on a number of these questions in our discussion of specific sections of the Proposed Rule and refer you to the relevant sections. These include:

- 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 – Proposed §§ 92.7, 92.8

- 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 – Proposed §§ 92.10, 92.11

- 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 communication – Proposed § 92.11

- 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. – Proposed § 92.204

- 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 – Proposed § 92.11

We do want to respond to HHS's last question—whether covered entities seek guidance on best practices for compliance with § 1557, and on what topics, we do wish to provide specific comments here. Our experience is a definite yes as we are often asked to provide these. While we greatly support the depth and breadth of the Proposed Rule, it necessarily has to apply to a huge range of covered entities, health programs and activities, and the Department's own activities. Thus we understand that the Proposed Rule must stay at a level applicable to the broadest array of activities and does not try to explain how it may apply to different types of covered entities. Yet that level of detail is critical to prevent discrimination rather than wait until discrimination occurs and individuals seek to enforce § 1557.

Once the Proposed Rule is finalized, we strongly urge HHS to work with each of its divisions to identify best practices, toolkits, and resources specific to those programs and activities. In our own experience, we are often asked for examples of best practices or toolkits by covered entities when we raise concerns about compliance. We believe HHS and its divisions can, and should, undertake steps to provide these details to covered entities. HHS has significant expertise in both program administration and investigations and enforcement of civil rights laws that make it uniquely suited to provide information about best practices to covered entities. The best practices likely will vary based on factors such as the program at issue, the setting, the size of a covered entity and many other factors. A best practice for a nursing home or assisted living facility is likely going to differ from a best practice for a small healthcare provider's office or a community clinic. And best practices will differ when providing assistance with applying for a program online, over the phone, or by mail. We believe HHS can, by working with the Office for Civil Rights and the Office of Minority Health as well as each of its operating divisions, identify areas where best practices would be most suited.

CONCLUSION

We have included numerous citations to supporting research, including direct links to the research. We direct HHS to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to comment on these important issues. If you have further questions, please contact Mara Youdelman, youdelman@healthlaw.org.

Sincerely,

Elizabeth G. Taylor
Executive Director