



October 3, 2022

Melanie Fontes Rainer
 Director, Office for Civil Rights
 U.S. Department of Health and Human Services
 200 Independence Avenue, S.W.
 Washington, D.C. 20201

Re: Section 1557, Nondiscrimination in Health Programs and Activities (RIN Number 0945-AA17)

Dear Director Fontes Rainer:

Thank you for the opportunity to submit comments on the Section 1557 Proposed Rule. Section 1557 of the Affordable Care Act (ACA) applies broadly to prohibit discrimination across a range of health programs and activities. Rulemaking finalized in 2020 (the 2020 Rule) weakened this critical protection based on a misreading of the statutory text and federal case law. We deeply appreciate the work of the Department of Health and Human Services (HHS or the Department) in reconsidering its approach and are gratified that the proposed rule would realign Section 1557 nondiscrimination regulations with the statute and federal nondiscrimination law.

The undersigned organizations represent millions of patients and consumers facing serious, acute and chronic health conditions across the country, including individuals who rely on the

patient protections provided under the ACA. Our organizations have a unique perspective on what patients need to prevent disease, cure illness and manage chronic health conditions. Our breadth enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion. We urge the Department to make the best use of the knowledge and experience our patients and organizations offer in response to this proposed rule.

In March of 2017, our organizations agreed upon three overarching principles¹ to guide any work to reform and improve the nation’s healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit (EHB) package.

Robust implementation — and subsequent enforcement — of Section 1557 will advance these shared principles by reducing discrimination and improving equitable access to quality, affordable care for all patients. We strongly support the proposed rule and urge that it be finalized promptly. We offer the following additional comments regarding specific aspects of the proposal.

Application of the Rule and Related Definitions

In general

Section 1557 prohibits discrimination in, among other places, “any program or activity that is administered by an Executive Agency *or* any entity established under” Title I of the ACA. The 2020 Rule decided this plain phrase was ambiguous and promptly narrowed the scope of the prohibition to include *only* Title I entities. That interpretation flatly contravenes the statute and has impermissibly limited nondiscrimination protections for consumers. We are therefore gratified that HHS has reexamined this issue and proposes to restore Section 1557’s nondiscrimination protections for all health programs and activities of the Department, as is required by the law. We strongly support this proposal.

Likewise, we commend the Department for proposing to reinstate regulatory definitions, jettisoned by the 2020 Rule, that clarify the circumstances in which non-federal entities are covered. Section 1557 applies outside the federal government to “any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.” The proposed rule would clarify that “Federal financial assistance” includes such assistance that the Department plays a role in providing or administering, including (but not limited to) advance payments of the premium tax credit and cost-sharing

¹ American Lung Association website, “Healthcare reform principles.” Available at: <https://www.lung.org/getmedia/0912cd7f-c2f9-4112-aaa6-f54d690d6e65/ppc-coalition-principles-final.pdf>

reduction payments made under Title I of the ACA. This language directly tracks the statutory text and we support its adoption.

We also strongly support the Department’s definition of “health program or activity.” The 2020 Rule advanced an incorrect understanding of this term, one wholly inconsistent with the statute it purported to implement, to justify the untenable conclusion that the ACA’s core nondiscrimination provision does not generally apply to health insurers. By contrast, the proposed definition of “health program or activity” would reestablish regulatory authority over, *inter alia*, entities principally engaged in providing or administering health insurance coverage or other health-related coverage. This approach aligns with the plain language of Section 1557, as well as the structure and purpose of the broader statute in which Congress situated it: a law designed in large part to improve access to comprehensive health insurance, including by eliminating insurance practices that pose barriers to coverage.

In addition, we strongly agree with the Department that a covered entity must comply with Section 1557’s nondiscrimination requirements across all of its operations. The proposed rule rightly observes that, because funds are fungible, federal financial assistance going to any part of a health program or activity necessarily benefits the entity receiving such funds, *as a whole*. Accordingly, the legal obligation not to discriminate, which accompanies such assistance, also must encompass the entire entity. This position is consistent with Section 1557’s broad construction, which notably applies to “any health program or activity, any part of which” receives federal funds. Indeed, a narrower construction, in which nondiscrimination rules apply only to part of a covered entity, makes it easier for discriminatory actors to structure their operations to evade liability and frustrates the purpose of the statute.

Application to excepted benefits and short-term limited duration insurance products

In a similar vein, we strongly support requiring a covered entity’s excepted benefits and short-term limited duration insurance products to adhere fully to Section 1557. Our organizations previously have expressed grave concerns about the harms to consumers posed by insurance products, such as these, which do not comply with the individual health insurance market reforms of the ACA.² These concerns are twofold. First, they relate to the products themselves, which exploit a lax regulatory environment to discriminate against consumers the plans do not want to enroll. For example, short-term plans frequently exclude or severely limit benefits for prescription medications, preventive services for women, contraception, and maternity care, restrictions that reduce coverage for, and discourage enrollment by, consumers with disabilities, women, and individuals who are or who may become pregnant.³ These products

² Letter to HHS regarding regulation of STLDI. Available at: <https://www.lung.org/getmedia/8a510945-cd82-41fe-968e-d83faf2292eb/013122-letter-to-hhs-re-regulation-of-stldi-policy-preferences-final.pdf>; *Under-Covered: How “Insurance-Like” Products Are Leaving Patients Exposed*. March 2021. https://www.ils.org/sites/default/files/National/undercovered_report.pdf .

³ Volk, J., et al. *Trump Administration Promotes Coverage That Fails to Adequately Cover Women’s Key Health Care Needs*. The Commonwealth Fund. October 2022. <https://www.commonwealthfund.org/blog/2020/trump-administration-promotes-coverage-that-fails-to-cover-womens-key-health-care-needs>; Palanker, D., Curran, E., *Limitations of Short-Term Health Plans Persist Despite Predictions That They’d Evolve*. The

are not subject to oversight of their provider networks, which may be designed in a way that limits care for LGBTQI+ people, individuals with disabilities, or people of color. And the products can, and do, charge higher prices, without limit, based on factors including an applicant's gender, age, or medical conditions.

Second, our concerns stem from the deeply problematic manner in which these products are often marketed. Numerous reports have documented sales practices that involve false or misleading statements and material omissions about coverage and efforts to screen out individuals based on their medical history.⁴

That these products do not have to abide by the ACA's individual market reforms does not relieve them of independent legal obligations under state and federal law, including Section 1557's prohibition on discrimination. Because the practices identified above implicate these nondiscrimination protections, they require greater scrutiny.

To that end, we respectfully request the Department provide additional guidance explaining how it intends to investigate potential violations by these (and similar) products and ensure their ongoing compliance with federal law. In recognition of the difficulty consumers have in bringing insurance-related problems to the attention of the relevant authorities, we urge HHS not to rely solely on complaints and to engage in proactive oversight in this area. For example, we suggest the Department collect data from covered entities describing the design features, take-up, and claims utilization of their short-term products, which when analyzed can provide indications of discriminatory practices. We also ask HHS to consider how best to coordinate with other regulatory bodies to test and study the marketing practices used by these entities.

Application to Medicare Part B

We support the proposal to include Medicare Part B funds within the definition of federal financial assistance, thereby bringing the recipients of those funds within the ambit of Section 1557's nondiscrimination requirements. The Department explains at length, and we agree, that for purposes of determining what constitutes federal financial assistance, payments to providers under Medicare Part B are functionally indistinguishable from provider payments authorized under Part A. Whether or not the Department's past approach of analyzing Part B funds differently was justified, we believe the proposal to align its treatment of Part A and Part B providers is wholly appropriate at present, in light of how the program now operates.

Commonwealth Fund. July 2022. <https://www.commonwealthfund.org/blog/2020/limitations-short-term-health-plans-persist-despite-predictions-theyd-evolve>

US House of Representatives, Committee on Energy and Commerce, *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk* https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyalMeg_Q-BJaURXX3/view

⁴ Government Accountability Office. Private Health Coverage: Results of Covert Testing for Selected Offerings. September 2020. <https://www.gao.gov/products/GAO-20-634R>

The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses. The Urban Institute. <https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses>

Recognizing that Medicare Part B funds constitute federal financial assistance is consistent with the text and purpose of Section 1557 and is likely to reduce confusion among Medicare beneficiaries. We urge the Department to finalize the change as proposed.

Prohibited Forms of Discrimination

General approach

As documented at length in the proposed rule, discrimination in health care contributes to disparities in health status and outcomes among communities of color, women, LGBTQI+ individuals, people with disabilities, individuals with limited English proficiency, older adults, and children. This discrimination can be particularly harmful for people with significant health care needs, including those who suffer from chronic conditions. Individuals with a chronic disease typically need to interact with more health care providers, on a more frequent basis, and often must rely on these providers, and their health insurance, to access lifesaving treatments. Discrimination may manifest in abusive interactions and care flatly denied; it may also result in high levels of stress that, among other things, directly increase individuals' health risks while also discouraging them from seeking care at all. Eliminating discrimination and its myriad barriers to care is critical for achieving better health outcomes for the millions of patients and consumers our organizations represent.

The proposed rule codifies a general prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability by any covered entity and supplements this protection by providing a non-exhaustive series of more specific examples of prohibited conduct. We are gratified by the strong restatement of nondiscrimination protections contained in these provisions and believe the additional clarity offered by the examples will help promote compliance by covered entities and a greater understanding by patients of the nondiscrimination protections to which they are entitled. We strongly support this approach.

Discrimination on the basis of sex

We strongly support the Department's proposal to clarify that Section 1557's prohibition on sex discrimination includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. This proposal advances the purpose of the statute by making clear that a range of forms of discrimination affecting LGBTQI+ individuals is unlawful and that prohibiting such misconduct is fully within the Department's authority. Just as fundamentally, it would also realign the regulation with federal civil rights case law. The 2020 Rule's understanding of sex discrimination was flawed from the beginning. Since the Supreme Court's ruling, in *Bostock v. Clayton County*, that discrimination on the basis of sexual orientation and gender identity constitutes prohibited sex discrimination under Title VII, it has been beyond doubt that the 2020 Rule's approach is at odds with federal law. We thank the Department for its hard work in reassessing these issues and for moving to correct the rule.

Nondiscrimination in health insurance and other health-related coverage

We reiterate our strong agreement with the Department's proposal to reapply Section 1557 nondiscrimination requirements to insurers and other issuers of health-related coverage. We also strongly support the Department's decision to identify specific actions by these entities that will constitute prohibited discrimination. We believe, in particular, that (1) the clear prohibitions on discrimination in connection with health services related to gender transition or other gender-affirming care are essential; and (2) consumers and covered entities will benefit from the inclusion of specific provisions describing nondiscrimination protections in the context of pregnancy and related conditions.

Discriminatory benefit design or marketing practices

We agree with the Department that the 2020 rule resulted in less protection for people who need health care and who are protected by Section 1557 against discrimination. We strongly support the application of Section 1557 to health insurance coverage, especially health benefit designs.

By enacting the ACA, Congress intended to prohibit health insurance practices, including plan benefit designs, that discriminate on the basis of race, color, national origin, sex, age, or disability. The ACA improved the availability and quality of health insurance by prohibiting medical underwriting and requiring community-rating, guaranteed issue, and coverage of pre-existing protections. The ACA also sought to ensure adequate benefits by creating the ten Essential Health Benefits (EHB) categories.

Section 1557 is key to achieving the goals of the ACA and enforcing its mandates, especially for people with disabilities and chronic conditions. People with disabilities frequently need multiple-high cost health care services. Without the prohibition on discriminatory marketing or benefit design, insurers will use marketing and benefit design to try to avoid enrolling people with disabilities in order to maximize their profits. For example, a health insurance plan may cover the fewest medications allowed in a category (anti-seizure medications, blood clotting medications, etc.) and place them all in the highest cost-sharing tier in order to discourage enrollment of people with epilepsy, hemophilia, and other conditions treated with medications. A plan might also arbitrarily limit rehabilitation services in order to reduce the services used by someone who acquires a disability during the plan year. Application of Section 1557 to marketing and benefit design is essential to protecting people with disabilities and other protected classes from insurers who will find roundabout ways to discourage their enrollment and undermine the protections for people with pre-existing conditions under the ACA.

Discrimination on the basis of sex and disability following the Dobbs decision

In the wake of the Supreme Court's recent decision ending the constitutional right to abortion, some providers have denied or limited access to certain medications that are indicated for conditions unrelated to pregnancy but that have side effects that may interfere with a pregnancy. For example, it has been widely reported that some providers have refused to dispense methotrexate, a drug commonly used to treat cancer and autoimmune diseases, because of its potential effects on pregnancy, even when the medication was prescribed for a

non-pregnancy-related reason.⁵ We are deeply concerned by these reports, which appear to document conduct constituting discrimination on the basis of sex and disability.

We know you are aware of these developments, and we were heartened by the Department's recent guidance reminding providers of their obligations under the federal civil rights laws, including Section 1557.⁶ We ask the Department to clarify prohibitions on such discriminatory conduct in the Section 1557 rule and fully investigate potential violations by any covered entity.

Discrimination in provider networks

We agree with HHS that health plan provider networks can be discriminatory in violation of Section 1557. While we also generally agree that it is outside the scope of Section 1557 rulemaking to codify extensive minimum standards for network adequacy akin to the standards specified in other federal regulations, we do believe it appropriate for the Department to provide instruction regarding the kinds of network design decisions that may violate the statute.

Networks that exclude or severely limit a category or categories of specialists have the effect of limiting or denying access to these providers' services, raising discrimination concerns. So too, do networks that lack accessible medical diagnostic equipment: in the absence of such equipment, an individual with a disability may be functionally without access to ostensibly in-network care. (We urge OCR to consider the lack of accessible medical diagnostic equipment in a provider's office as discrimination under Medicare Part B as well). A network may also be discriminatory if it fails to provide culturally- and linguistically-competent care. This means, among other things, that networks must ensure access to culturally appropriate care that reflects the diversity of enrollees' backgrounds and is attuned to traditionally underserved communities, including people of color, immigrants, and LGBTQI+ individuals.

Accessible medical diagnostic equipment

As HHS has identified, people with disabilities continue to "fare worse on a broad range of health indicators than the general population."⁷ These disparities in health outcomes are closely linked to a lack of timely access to quality primary and specialty health care services, including the services necessary to treat the chronic conditions that our organizations address. For example, adults with disabilities are significantly less likely to receive preventative and diagnostic health services, including primary care appointments, cervical cancer screenings, and mammograms.⁸ Disparities in access to care can be traced, in part, back to a widespread lack of

⁵ See, e.g., <https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/>

⁶ <https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html>

⁷ 87 Fed. Reg. 47836.

⁸ 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

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.⁹ For example, a recent study of nearly 4,000 primary care offices in California found that only 19 percent of facilities had accessible examination tables, and only 11 percent of facilities had accessible scales.¹⁰ Even when provider facilities have accessible MDE, staff is often not properly trained in how to use the equipment, leading to underutilization.¹¹

To address this, we encourage the Department to incorporate the 2017 Standards for Accessible Medical Diagnostic Equipment published in 2017 by the US Access Board into these regulations. The MDE Standards, which implement Section 510 of the Rehabilitation Act, set forth minimal technical criteria for the accessibility of MDE in facilities where health programs or activities are conducted.¹² Incorporating these standards into Section 1557 is a necessary step towards improving access to health care services for individuals with disabilities.

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. We encourage the Department to require that these notices be provided in plain language including in non-English languages. In addition to the current requirements, we also recommend including a requirement that, if a covered entity will not provide certain services due to a religious belief, then it must include that information on the notice and provide it in the required non-English languages.

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

We strongly support this provision and the requirements for when this notice must be made available. We also recommend that if a covered entity operates across multiple states, that the covered entity has to provide the notice in not merely the top 15 languages in the aggregate (that is, across all the states) but rather a total of the top 15 languages in each state. We also recommend that OCR require covered entities to provide the notice in large print, at least 18-point font, as well as in the top 15 languages. This will allow individuals with certain vision impairments to access the notice.

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/>.

⁹ 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>

¹⁰ 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/>.

¹¹ NCD Report, *supra* note 18, at 16.

¹² 29 U.S.C. § 794f; 36 C.F.R. pt. 1195.

Further, we recommend that Department specify that this notice must be provided at the beginning or on the first page of any document. Unfortunately, many documents in which this notice will be required can be lengthy. We do not believe a person with limited English proficiency (LEP) would look through multiple pages of a document in English if the notice is only at the end. Given the importance of this notice, we believe it should be the first page that the reader sees. This will benefit LEP individuals who will see information in their language and individuals with disabilities who will see information in large print. Notices in English and non-English languages should be provided in plain language.

As was previously done, we also suggest that Department develop and provide covered entities with model notices and translated information in the relevant languages that will be needed across the country. These notices should be specific to the different types of publications they are included on; that is, a notice for a consent form would be different from one with information about a public health emergency or notice of one's rights or benefits.

Meaningful access for limited English proficient individuals

We support the provisions related to meaningful access, including the requirements related to machine translation. Regarding the section on "evaluation of compliance," we have concerns about the lack of a requirement to develop a language access plan. We appreciate that the Department 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 a covered entity to gather information about the needs of LEP individuals in its service area prior to developing policies and procedures.

We also support the clarification in the 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, a minor can only be used to interpret in an emergency, and an adult accompanying an adult should not act as an interpreter without the person's consent or in an emergency. The proposed rule adds an expectation that in an emergency situation, the reliance on an accompanying adult or minor should be "a temporary measure." We support this addition.

We appreciate the restoration of requirements related to video interpreting. The 2020 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.

We also recommend that the Department 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 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.

Effective communication for individuals with disabilities

We support the provisions in this section regarding effective communication for people with disabilities. Effective communication is critical to ensuring that people with disabilities have access to quality health care. We also note that since the Rehabilitation Act Section 504 rules were first issued, the basic duty to assure effective communication has revolved around the requirement to provide auxiliary aids and services. The provision of auxiliary aids and services is a necessary but far from a sufficient tool for avoiding and remedying effective communication discrimination. This is particularly true with regard to the estimated four to five million children, youth, working-age people, and older adults who cannot rely on natural speech to effectively communicate with most others.¹³ Instead, such individuals require, but all too frequently lack meaningful, effective access to the robust language-based alternative and augmentative communication (AAC) they need to express themselves and be understood.

We appreciate that HHS OCR has taken repeated actions throughout the pandemic to prevent and remedy this form of insidious discrimination. We urge HHS to incorporate the following OCR guidance directly into the final regulations as well as all its subsequent guidance, technical assistance, and enforcement activities: [Non Discrimination in Standards of Care -- March 28, 2020](#); and, [The Rights of Persons with Disabilities to Have Reasonable Access to Support Persons in Hospital Settings During COVID-19-- June 9, 2020](#).

Integration

Section 1557 explicitly references Section 504 of the Rehabilitation Act, which has regulatory requirements to provide services and programs in the most integrated setting appropriate to the needs of individuals with disabilities. Section 504 has consistently been interpreted as requiring those receiving federal financial assistance to not segregate individuals with disabilities from their communities.¹⁴ Importantly, Section 504 also prohibits covered entities

¹³ Beukelman DR, Light J. *Augmentative and alternative communication: Supporting children and adults with complex communication needs*. 5th ed. Baltimore, MD: Paul H. Brookes Publishing Co.; 2020.

¹⁴ 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 Section 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 Circ. 2016) (finding integration mandate violations because the

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.¹⁵ Therefore, covered entities under Section 1557 are prohibited from providing health programs and 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.

We are extremely glad that the Department has provided an explicit mention in the regulatory text and extensive discussion in the proposed rule about the details of this discrimination. We strongly support the proposal’s specific mention of “utilization management practices, provider reimbursement, contracting out to third party-contractors such as PBMs, and quality measurement and incentive systems” as areas where covered entities should pay careful attention. We also agree with the Department’s examples of plans requiring prior authorization or step therapy or other utilization management when individuals are accessing a medication in the community, but not using these tools when individuals are in institutions would count as discrimination.

We would expand on these examples in response to the Department’s question about scope and nature of this protection, including benefit designs which hinder an individual’s community participation or increase risk of institutionalization. We urge OCR to investigate aspects of health coverage that may result in more isolation and segregation of individuals with disabilities, including prescription drug formulary design, utilization management practices, and network adequacy. Examples include:

- Specialist services covered for those in institutions but not in the community,
- Retroactive coverage of nursing facilities but not home and community-based services, and
- Coverage of hospitalization for mental health services but not community-based services.

Nondiscrimination in the use of clinical algorithms in decision-making

The preamble to the proposed rule provides numerous documented examples of bias from clinical algorithms. Many clinical algorithms, including those that assess risk of disease, dictate that Black patients, in particular, must be more ill than white patients before they can receive treatment for a range of life-threatening conditions, including for kidney disease, heart failure, and pregnancy-related complications. There are also clinical algorithms that may result in discrimination against individuals with disabilities and older adults.

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).

¹⁵ 45 C.F.R. 84.4(b)(4).

That said, we point to the numerous examples of bias, discrimination, and harm by covered entities by automated decision-making tools and models that may fall outside the term “clinical algorithm.”¹⁶ Such examples of harm include assessment tools for home and community-based services for both level of care determinations and services allocation that discriminate against groups or deny services needed to maintain community integration, and eligibility systems for Medicaid, CHIP, or Marketplace coverage that wrongfully deny or terminate coverage.¹⁷

The preamble to the rule recognizes this broader definition, noting that clinical algorithms can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models. We therefore request that the Department include in the final rule a broad definition of clinical algorithms that encompasses any form of automated or algorithmic decision-making system for care or health care enrollment in order to capture the prevalence and variety of automated decision making systems used by covered entities. In the absence of a definition, the term “clinical algorithms” may be too narrowly construed and may allow some to consider excluding, for example, the Crisis Standard of Care Plans cited in the preamble as not “clinical algorithms” under a narrow definition because many were policies or ranking systems rather than automated decisions.

Nondiscrimination in the delivery of health programs and activities through telehealth services

We appreciate the proposed rule’s inclusion of telehealth and the recognition of 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. While telehealth has been useful for all populations, the preamble rightly notes the evidence that telehealth availability and use has not been equitable, particularly for LEP patients, for people with disabilities, and for patients who are blind or deaf. Too often telehealth platforms, software, and applications don’t accommodate the needs of these patients.

As a basic step, the Department should require telehealth platforms to allow a third-party interpreter or use of auxiliary aids and services. Second, this requirement should include all of the communication about telehealth that occurs prior to a telehealth appointment, for example, scheduling, system requirements, testing connections, telehealth appointment reminders, and log-on details – all must be accessible to people with LEP and people with disabilities. Similarly, platforms should be adopted 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.

¹⁶ Edwards, E., et al. NHeLP AHRQ Comments. National Health Law Program. June 10, 2021.

<https://healthlaw.org/resource/nhelp-ahrq-comments/>

¹⁷ Edwards, E. Preventing Harm from Automated Decision-Making Systems in Medicaid. National Health Law Program. June 14, 2021. <https://healthlaw.org/preventing-harm-from-automated-decision-making-systems-in-medicaid/>

Thank you for the opportunity to provide these comments. If you have any questions contact Rachel Patterson, Senior Director of Federal Relations & Policy, Epilepsy Foundation, at rpatterson@efa.org.

Sincerely,

American Cancer Society Cancer Action Network
American Kidney Fund
American Liver Foundation
American Lung Association
Arthritis Foundation
Asthma and Allergy Foundation of America
Cancer Support Community
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Lupus Foundation of America
Muscular Dystrophy Association
National Alliance on Mental Illness
National Eczema Association
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
Pulmonary Hypertension Association
Susan G. Komen
The AIDS Institute
The ALS Association
The Leukemia & Lymphoma Society
WomenHeart: The National Coalition for Women with Heart Disease