No. 18-35846

# In The United States Court Of Appeals For The Ninth Circuit

ANDREA SCHMITT and ELIZABETH MOHONDRO,
each on their own behalf, and on behalf of all similarly situated individuals,

*Plaintiffs-Appellants,*
v.

KAISER FOUNDATION HEALTH PLAN OF WASHINGTON, KAISER FOUNDATION HEALTH PLAN OF WASHINGTON OPTIONS, INC., KAISER FOUNDATION HEALTH PLAN OF THE NORTHWEST, AND KAISER FOUNDATION HEALTH PLAN, INC.,

*Defendants-Appellees.*

*On Appeal from the United States District Court for the Western District of Washington*

## PROPOSED BRIEF OF THE NATIONAL HEALTH LAW PROGRAM AND NORTHWEST HEALTH LAW ADVOCATES AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS.


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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1(a), the undersigned counsel certifies that the *amici curiae*, National Health Law Program (NHeLP) and Northwest Health Law Advocates (NoHLA) (collectively, "NHeLP *et al.*"), are not subsidiaries of any other corporation and no publicly held corporation owns 10 percent or more of any *amici curiae* organization's stock.

Dated: January 29, 2019

/s/ Sarah Somers
Sarah Somers

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## INTEREST OF AMICI[1]

The *amici curiae* are the National Health Law Program (NHeLP) and Northwest Health Law Advocates (NoHLA). NHeLP is a 50-year old public interest law firm that works to advance access to quality health care and to protect the legal rights of lower-income people and people with disabilities. NHeLP engages in education, policy analysis, administrative advocacy, and litigation at both state and federal levels. NoHLA is a non-profit legal organization focused on promoting access to comprehensive, affordable health care for Washington State residents, with special attention to the needs of low-income and vulnerable populations. NoHLA has a strong interest in ensuring that individuals disabled from hearing loss are able to access needed care and are not subject to discrimination based on their disability.

While each *amicus* has particular interests, they share the mission of ensuring that all people in the United States have access to affordable, accessible, and dependable health care not impeded by discrimination based on race, age, sex, or disability. *Amici* NHeLP *et al.* have a long history of helping to ensure that American families and individuals can obtain the quality health care to which they

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), counsel for *amici curiae* states that no counsel for a party authored the brief in whole or in part, and no person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

are entitled, through policy advocacy, education, and litigation that holds federal, state, and private entities their health-related programs. *Amici* NHeLP *et al.* have a deep knowledge about the Affordable Care Act (ACA) and disability discrimination. *Amici* NHeLP *et al.* obtained consent of Plaintiff-Appellants file an amicus brief in this matter, but upon request to Defendant-Appellee's were told they did not yet have client authority to consent.

## INTRODUCTION

Congress significantly changed both access to, and comprehensiveness of, health insurance coverage when it enacted the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148 (2010), as amended in the Health Care and Education Reconciliation Act, Pub. L. No. 111-152 (2010). Before the ACA was enacted, individuals with disabilities and chronic health conditions were commonly denied or terminated from health insurance coverage, faced annual and lifetime benefit limits, and could not find affordable coverage.[2] Even if a person with a disability or chronic health condition could find health coverage, it would often exclude pre-existing conditions or otherwise deny benefits based on health status or disability. Many of these discriminatory practices had been challenged in courts, but plaintiffs generally found success in only narrow circumstances. Congress explicitly tackled many of the discriminatory policies used by health insurers to help minimize costs and risks, such as lifetime limits on coverage, and

[2] *See generally, e.g.,* Valarie K. Blake, *An Opening for Civil Rights in Health Insurance After the Affordable Care Act*, 36 B.C. J. L. & Soc. Just. 235 (2016) (describing pre-ACA health insurance discrimination and the ACA changes that addressed those issues); Sara Rosenbaum et al., *Crossing the Rubicon: The Impact of the Affordable Care Act on the Content of Insurance Coverage for Persons with Disabilities*, 25 Notre Dame J. L. Ethics & Pub. Pol'y 235 (2014) (describing ACA nondiscrimination provisions generally and focusing the function of essential health benefits).

outlawed them in plans covered by the law. In the ACA, Congress did not require every health insurance plan to be a Cadillac plan offering every possible service, but it did require that a health insurance plan be a functioning vehicle with certain minimum features that would carry a person along in their health care journey without dropping them suddenly or denying further care because of their race, age, sex, or disability.

Section 1557 of the ACA is an important component of the law's guarantee of coverage, as it prohibits discrimination in most health programs, including many private insurance plans. 42 U.S.C. § 18116(a). Section 1557 prohibits discrimination based on race, color, national origin, sex, age, and disability and creates a private right of action for individuals to complain of such discrimination. It incorporates the remedies of major civil rights statutes, however, pre-ACA case law is not necessarily instructive when determining the scope of protections and remedies post-ACA, including whether plan design is discriminatory. This is because the ACA significantly changed the obligations of covered entities. The ACA prohibits certain practices that were long standard among health insurers and that had survived legal challenges asserting discrimination. Thus, as the landscape of health insurance has shifted significantly, so too must evaluations of what constitutes discrimination in health coverage. Courts asked to address such claims must follow this shift and carefully navigate this new landscape using the language

of the statute and agency interpretation. In this case, the District Court erred in its interpretation of Section 1557 and overly relied on pre-ACA cases regarding disability discrimination to dismiss the Plaintiffs' claims for disability discrimination. The case should be remanded to allow for discovery to determine whether the plan has discriminated against the Plaintiffs.

## ARGUMENT

### I. The Affordable Care Act Changed How Health Insurance Plans Offer and Provide Coverage to Eliminate Long-standing Discriminatory Practices

The ACA changed the private insurance industry by significantly expanding the population covered and prohibiting many of the methods used by insurers to avoid costs. Before the ACA, the business model of health insurance incentivized insurers to avoid covering individuals who would have high health needs or who would otherwise be costly to the plan. While there were some state and federal restrictions on limits in coverage, insurers had a large array of mechanisms at their disposal to deny enrollment, limit benefits, and impose high costs on the insured. The ACA ushered in significant protections for individuals in several different areas, including enrollment, cost-sharing, and benefit design and provision. The ACA made sweeping reforms to expand coverage and improve the scope and quality of health insurance. This includes mandating coverage of certain preventive services and requiring that covered insurance plans provide certain "essential

health benefits (EHBs). The ACA also shifted regulation of health insurance coverage from largely state-based insurance law to include greater federal oversight. *See* Rosenbaum et al., *supra* n. 2, at 529-30. The law significantly changed how insurers could legally make choices about the content of their plans, how they could control risk of excessive spending, and the bases for denying or limiting services.

However, this does not mean that the ACA requires that all health insurance plans cover all treatments for all people at minimal costs to the individual. Rather, the reforms of the Act work to create access to affordable coverage and ensure that the coverage offered was comprehensive and did not deny services on an arbitrary or discriminatory basis. 42 U.S.C. § 300gg-6 (describing comprehensive coverage as that which includes the EHBs required in 42 U.S.C. § 18022). Insurance plans would still vary in terms of cost-sharing, the network of providers offered, and other factors. The ACA did not eliminate all mechanisms by which plans can limit the benefits offered or deny coverage of requested services. While insurers cannot base premium rates on health status, disability, or other factors, they can vary premium rates on coverage of an individual or family, rating area, age (with limitations), and tobacco use. 42 U.S.C. § 300gg. Plans may also use clinically indicated, reasonable medical management techniques when approving or denying services. 45 C.F.R. § 156.125; *see also* ACA; HHS Notice of Benefit and Payment

Parameters for 2016 Final Rule, 80 Fed. Reg. 10750 (Feb. 27, 2015) (hereinafter "BPP Rule"). Insurers may also make use of the annual out-of-pocket limits that shift costs back to the insured, such as uniform copays and deductibles. 42 U.S.C. § 18022(c); 42 U.S.C. §300gg-6 (limiting cost-sharing and setting maximums); *see also* Blake, *supra* note 2, at 256 (discussing penalty for violating cost-sharing requirements).[3] Group and individual insures may also vary premiums based on participation in employer wellness programs, although those programs also may not discriminate. 42 U.S.C. § 300gg-4; *id.* § 300gg-4(j) (regarding wellness programs); 42 U.S.C. §300gg-18 (regarding rate setting). The Act also sets up a rating system for plans offered on the marketplaces, dividing plans into bronze, silver, gold, and platinum and requiring a mechanism to allow individuals to compare plans.[4] 42 U.S.C. §§ 18022(a); 18022(d).

[3] As with any method insurers have to limit costs, cost-sharing must not discriminate on the basis of disability. This could include financially prohibitive cost sharing targeted at benefits disproportionately relied upon by people with disabilities.

[4] The District Court in *Schmitt v. Kaiser Found. Health Plan Wash.*, No. C17-1611, RSL, 2018 WL 4385858, at *2 (W.D. Wash. Sept. 14, 2018) misunderstood what a "gold level" plan is. A gold plan does not offer more benefits, but rather charges insureds more in premiums so they may have lower deductibles and co-payments. 42 U.S.C. § 18022(d)(1)(C).

### A. The ACA made illegal many health insurance practices that formerly survived disability discrimination challenges

Before the ACA, insurers commonly imposed caps on the amount of a benefit for a particular condition (such as limits on numbers of visits) or general caps on lifetime benefits. For example, plans might place a $25,000 limit on coverage for AIDS-related conditions in either a year of the plan or the plan's lifetime. Individuals harmed by such limits attempted to challenge them on the basis of that they discriminated against individuals with disabilities. Judges repeatedly ruled against such plaintiffs finding that the non-discrimination laws focused on access to a policy rather than the coverage content within the policy, and that regulation of insurance was the purview of state insurance commissions. *See, e.g.*, *McNeil v. Time Ins. Co.*, 205 F.3d 179, 182 (5th Cir. 2000) ($10,000 limit on coverage for AIDS-related care was not disability discrimination); *Doe v. Mut. of Omaha Ins. Co.* 179 F.3d 557, 588 (7th Cir. 1999) (policies with lifetime limits did not discriminate based on disability and regulating insurance was the purview of the state insurance commissioner); *McGann v. H&H Music Co.*, 946 F.2d 401, 403 (5th Cir. 1991) (permitting a lifetime limit on benefits); *Modderno v. King*, 82 F.3d 1059, 1062 (D.C. Cir. 1996) (permitting $75,000 lifetime cap on mental health benefits even though there was no comparable limit on physical health benefits). The ACA directly changed this view of disability discrimination in

health insurance.[5] It explicitly prohibits annual dollar limits, eliminates lifetime limits, and sets maximum out of pocket limits. 42 U.S.C. § 300gg *et seq*.

Other challenges to limits and exclusions in health insurance based on disability discrimination commonly came up against the barrier imposed by *Alexander v. Choate*, 469 U.S. 287 (1985). After *Choate*, plaintiffs challenging disability discrimination in health insurance using Section 504 of the Rehabilitation Act were typically successful if they could show that they were denied access to the benefit—such as being denied enrollment. Challenges to the content or adequacy of the benefit often failed. *See, e.g., Rome v. MTA/N.Y. City Transit*, No. 97-CV-2945 (JG), 1997 WL 1048908, at *4 (E.D.N.Y. Nov. 18, 1997) (speech therapy not covered for autism but for other conditions); *see also* Samuel R. Bagenstos, *The Future of Disability Law*, 114 Yale L. J. 1, 41 nn.168-70 (2004) (listing cases where courts did not analyze whether of content of benefits was discriminatory when they excluded things on the basis of treatment or diagnosis). *Choate* did not at all preclude claims based on content of a benefit, but they were

[5] The ACA expanded mental health parity requirements to types of health insurance not already required to have parity. A lack of comparability between physical health and mental health benefits had been addressed for most health insurance plans and programs through the Mental Health Parity Act, Pub. L. 104-204 (1996) and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, Pub. L. 110-343 (2008).

rarely successful. However, the ACA directly addressed both discrimination in access to health insurance *and* in benefit design, content, and provision.

The Americans with Disabilities Act ("ADA") has also been an ineffective tool for individuals to address discrimination in health insurance, largely because the ADA specifically has a "safe harbor" provision. Importantly, Section 1557 references Section 504 which has no such safe harbor provision. The ADA's safe harbor provision says the statute "shall not be construed to prohibit or restrict" insurers and others from establishing or administering benefit plans that "are based on underwriting risks, classifying risk, or administering risks that are based on or not inconsistent with State law." 42 U.S.C. § 12201(c). Although the statute goes on to say that the safe harbor provision "shall not be used as subterfuge to evade the purposes of [the ADA]," many of the cases relying upon the ADA to challenge discriminatory health insurance decisions did not even reach the subterfuge question and rejected claims based on the access and content distinction. *Id.; see, e.g., Doe v. Mutual of Omaha, Ins.*, 179 F.3d at 559. The question of subterfuge has therefore led to much litigation and confusion, including whether the provision requires discriminatory intent or if subterfuge need not be intentional, but simply be a decision not based on sound actuarial principles. *Compare Leonard F. v. Israel Discount Bank of N.Y.*, 199 F.3d 99 (2d Cir. 1999), with *Doukas v. Metropolitan Life Ins. Co.*, 950 F. Supp. 422 (D.N.H. 1996).

Before the ACA, insurers were allowed to engage in many practices that were discriminatory, yet had not been found to be illegal. The ACA explicitly and purposefully created standards for health insurance that included both access and content, established a basic structure for comprehensive health coverage through the broad categories of EHBs, and included oversight and enforcement mechanisms that were all in addition to existing protections. Therefore, claims of discrimination in health insurance after the ACA must be examined in the context of the ACA changes, especially when considering disability discrimination.[6]

### B. Congress explicitly created protections against discriminatory practices in plan content

The ACA did not only protect individuals from discrimination preventing access to affordable health insurance. Congress also included multiple provisions that addressed the content of plans and banned discrimination in the scope of coverage to ensure provision of the comprehensive health insurance the Act envisioned. Many states have laws imposing specific coverage mandates, such as requiring plans to provide applied behavior analysis therapy for people with autism. However, the ACA has a more comprehensive approach to ensuring that

[6] While insurers must meet new standards regarding how they manage their risks, the ACA also included other market reforms to alleviate some of this burden in the form of medical loss ratios and risk adjustment, reinsurance, and risk corridors. Blake, *supra* note 2, at 280-81.

plans offer necessary benefits and do not discriminate in the provision of those benefits.

As noted above, under the ACA, plans were required to provide comprehensive health insurance coverage that included "essential health benefits" ("EHBs"). 42 U.S.C. § 300gg-6. The statute requires coverage of ten general benefit categories as defined by the Secretary of Health and Human Services ("HHS") and the services that fit within categories. 42 U.S.C. § 18022(a)-(b). HHS authorized states to select a benchmark plan to serve as the standard for plans required to offer EHB in the state. States that do not select a benchmark plan would have the default benchmark plan as defined by HHS. 45 C.F.R. § 156.110. Insurers cannot comply with EHB requirements if their coverage discriminates. 42 U.S.C. § 18022(4).[7] The statute also provides for bronze, silver, gold, and platinum level of coverage designations and limits cost-sharing for individuals. The HHS Secretary is required to review the EHB package, including for whether it covers a diverse population and does not make coverage decisions in ways that discriminate, as well as periodically update it to address any gaps or changes in the evidence base. 42 U.S.C. § 18022(a)(4). The EHB framework is designed to ensure

[7] HHS recognized that EHB benchmark plans may not reflect all plan requirements, including non-discrimination. *See* BPP, 80 Fed. Reg. at 10822.

access to a broad array of necessary services that effectively meet the health care needs of most individuals.

The statute describing the EHB requirements explicitly states, "the Secretary shall . . . not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability or expected length of life[.]" 42 U.S.C. § 18022(b)(4)(B). The EHB design must also take into account health needs of a diverse population, including those with disabilities, and ensure that the EHBs not be subject to denial based on factors that include disability. *Id.* § 18022(b)(4)(C)-(D). The EHB categories are broad and intended to provide "comprehensive" coverage. 42 U.S.C. § 300gg-6.

The ACA also creates mechanisms for state and federal compliance monitoring. States largely enforce compliance with EHB standards, while HHS conducts compliance reviews and monitoring. CMS, Ctrs. Medicare & Medicaid Servs, Final 2016 Letter to Issuers in the Federally-Facilitated Marketplace 37-38 (Feb. 20, 2015)(hereinafter "2016 Letter to Issuers").[8] Individuals may also file

[8] The guidance in the Letters to Issuers applies to plans sold through the federally facilitated marketplaces and state based marketplaces using the federal platform, HHS encourages state-based marketplaces follow the guidance for plan review and other functions. All of the Letters to Issuers can be found on the CMS, Center for Consumer Information & Insurance Oversight (CCIIO) resources website, https://www.cms.gov/CCIIO/Resources/Letters/index.html.

complaints with their state insurance commissioners and the HHS Office for Civil Rights ("OCR"). *See, e.g.,* 45 C.F.R. § 92.302. Individuals may also file complaints. Importantly, Congress also included Section 1557 in the ACA, which created a health care specific civil right that addressed discrimination in access to coverage and specifically prohibited discrimination in health care itself, including health care coverage.

Congress crafted Section 1557 using the broad language of long-standing civil rights statutes:

> [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.

42 U.S.C. § 18116(a). Importantly, Section 1557 incorporates Section 504 of the Rehabilitation Act of 1973. 29 U.S.C.§ 794.

As part of the ACA's framework of nondiscrimination protections, Congress and HHS expressly prohibited insurers from designing plan benefits and employing marketing practices that discourage persons with disabilities from enrolling. Section 1557 of the ACA is the key to enforcing the ACA's reforms. As directed by the statute, HHS determined that Section 1557 prohibits discrimination

on the basis of disability in how ACA-regulated health plans design and administer benefits:

> A covered entity shall not, in providing or administering health-related insurance or other health related coverage…have benefit designs that discriminate on the basis of…disability.

45 C.F.R. §92.207(b)(2). HHS, including its OCR, has issued both regulations and sub-regulatory guidance about how to evaluate claims of discrimination under Section 1557.[9] This guidance includes a variety of examples as well as mechanisms for evaluating plan benefit design for discrimination. As described in Section II.A *infra*, HHS has set forth multiple approaches for such evaluations, which reflects the in-depth examination that will often be required and shows that one test may be insufficient for identifying all instances of discrimination. For example, HHS recognized the need for multiple mechanisms for compliance in the regulations for Section 1557 when it specifically declined to provide that compliance with EHB requirements would automatically constitute compliance with Section 1557. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31377 (hereinafter "Section 1557 Final Rule"). However, despite

[9] As agency interpretation of a statute it is charged with enforcing, courts have looked to OCR guidance to determine what constitutes discrimination under Section 1557, finding it persuasive. *See, e.g., Rumble v. Fairview health Servs.*, No. 14-CV-2037 SRN/FLN, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (citing *Skidmore v. Swift*, 323 U.S. 134, 140 (1944)).

coverage requirements and multiple mechanisms for reviewing plans, discrimination is sometimes difficult to identify. While some discrimination is facial, it may manifest as a practice or as a policy applied to an individual's circumstances. Even in cases where the discrimination may seem clear, there may still be investigation and analysis to understand the extent of the problem. HHS recognized the need for multiple mechanisms for evaluating compliance when it "decline[d] to adopt a deeming approach" that compliance with EHB requirements would automatically constitute compliance with Section 1557. Section 1557 Final Rule, 81 Fed. Reg. at 31377-78; *see also id.* at 31431 (declining to deem compliance with 1557 based on compliance with other federal laws citing the potential harmful consequences to individuals' health that may occur if covered entities do not adhere to civil rights obligations).

## II. Evaluating Discrimination in Plan Benefit Design Demands a Fact-based Analysis that Tracks the ACA's Protections

HHS has identified a number of forms of discriminatory plan benefit design, including arbitrary coverage exclusions, high cost sharing for the treatment of certain conditions, and the over-use of utilization management for certain conditions or treatments. BPP Rule, 80 Fed. Reg. at 10822. Although denial of coverage of hearings aids is not listed as an example of disability discrimination, HHS does indicate that covering hearing aids is not out of the norm as it is an

example of potential age discrimination to provide hearing aids to children and not older adults. 2016 Letter to Issuers, at 45. Features of plan benefit design such as cost sharing and coverage exclusions are not discriminatory *per se*, as the district court posited and rejected. Rather, insurers can take these features of plan benefits and design them in a way to discriminate against classes of individuals. For example, as explained below, HHS agreed that placing all drugs used in the treatment of HIV at the highest cost-sharing level for prescription drugs, including generics, would be discriminatory. BPP Rule, 80 Fed. Reg. at 10822.

HHS has developed several methodologies for evaluating plan benefit design to identify discriminatory practices and stop insurers seeking to circumvent the ACA's protections for persons with preexisting conditions.[10] HHS identified a list of medical conditions that it would use to evaluate plans for discriminatory benefit design, including: bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia, noting that it may examine other medical conditions in future years. CMS, Ctrs.

[10] *See* 2017 Letter to Issuers, at 46 (Feb. 29, 2016), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf.

Consumer Info. & Ins. Oversight, Final 2017 Letter to Issuers in the Federally-facilitated Marketplace 48 (Feb. 29, 2016) (hereinafter "2017 Letter to Issuers").[11]

### A. The trial court failed to use methodologies established by the Department of Health and Human Services to evaluate plans and identify discriminatory benefit design

HHS recognized that evaluating plan benefit design requires a fact-based, case-by-case analysis. Accordingly, in the final rulemaking for Section 1557, HHS declined to establish a bright line test for when a plan design is discriminatory. Section 1557 Final Rule, 81 Fed. Reg. at 31434. Instead, HHS cited to various examples of discriminatory benefit design provided in earlier rulemaking and guidance. *Id.* at 31434, n. 258. These include plans that place all drugs used to treat a certain medical condition in the highest cost sharing tier, a practice known as "adverse tiering" to discourage enrollment, for example, by people with HIV. In the final rule implementing Section 1557 and guidance cited therein, HHS describes the methodologies it will employ to evaluate whether a plan benefit design is discriminatory. These include an analysis of discriminatory intent in

[11] Last year, HHS announced that it would not conduct further plan reviews in 2018 and beyond. *See* CMS, Ctrs. Consumer Info. & Ins. Oversight, Guidance to States on Review of Qualified Health Plan Certification Standards in Federally-facilitated Marketplaces for Plan Years 2018 and Later (April 13, 2017), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QHP-Certifcation-Reviews-Guidance-41317.pdf.

benefit design, conducting an outlier analysis of cost sharing and other plan elements; and an analysis to evaluate how treatments for select medical conditions align with clinical guidelines and the standard of care. A court analyzing a claim of discrimination should rely on methodologies developed by HHS to evaluate plans for discriminatory benefit design.

**1. Discriminatory intent analysis**

In the preamble to the final rule for Section 1557, HHS describes concerns and questions with which it will evaluate plans for discriminatory benefit design, including intentional discrimination. These include:

- Did the entity use a neutral rule or principle?
- Was the reason for the coverage decision a pretext for discrimination?
- Is coverage for the same or a similar service/treatment available to individuals outside the protected class or those with different health conditions?
- What are the reasons for any differences in coverage?

Section 1557 Final Rule, 81 Fed. Reg. at 31429-33. As HHS noted, "we do not affirmatively require covered entities to cover any particular treatment, as long as the basis for exclusion is evidence-based and nondiscriminatory." Section 1557 Final Rule, 81 Fed. Reg. at 31433-4.

Discerning whether a benefit exclusion, cost sharing structure, or other design feature is a pretext for discrimination is a fact-based inquiry. Discriminatory intent may be manifest, such as with coverage exclusions for gender affirming

care; or could be revealed by whistle-blowers or through discovery. While it has limited usefulness for evaluating plan benefit design, the general framework for identifying discriminatory benefit design serves as the basis for the other methods developed by HHS to evaluate plans, as described below.

**2. Outlier analysis**

In its Letter to Issuers cited to in the Section 1557 Final Rule (and reaffirmed in subsequent Letters to Issuers issued thereafter), HHS describes the outlier analysis it will employ for reviewing plans for discriminatory benefit design, as well as providing a toolkit for states conducting their own analysis. HHS reviews prescription drug formularies to for "outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular USP category and class." 2016 Letter to Issuers, at 40. HHS also examines plans' cost sharing structures outlier analysis will compare benefit packages with comparable cost-sharing structures to identify cost-sharing outliers with respect to specific benefits. Section 1557 Final Rule, 81 Fed. Reg. at 31434; 2016 Letter to Issuers, at 38.

As an example of using the outlier analysis, the National Health Law Program used this approach to identify discriminatory plan benefit design in a

2014 administrative complaint filed with HHS OCR.[12] The National Health Program joined The AIDS Institute, a Florida-based HIV/AIDS advocacy organization, which analyzed the prescription drug formularies for 36 silver-level plans sold through the Florida marketplace. Plans sold by four insurers—Cigna, Aetna, Humana, and Preferred Medical—stood out because they placed every commonly prescribed HIV/AIDS medication, including generic drugs, into the highest cost sharing tiers. The analysis found that other issuers with varied tiering or placed HIV drugs on more affordable tiers. HHS agreed that placing all drugs used to treat a certain medical condition in the highest cost sharing tiers is a discriminatory plan benefit design prohibited under the ACA. Section 1557 Final Rule, 81 Fed. Reg. at 31434, n. 258; BPP Rule, 80 Fed. Reg. 10822. Subsequently, the pharmaceutical trade industry association PhRMA contracted for an analysis of the formularies for 123 silver marketplace plans and found similar problems regarding multiple sclerosis and cancer. PhRMA concluded that there was a "lack of adequate formulary scrutiny on the part of state and federal regulators" because "[r]equiring high cost sharing for all medicines in a class is exactly the type of

[12] *See* National Health Law Program & The AIDS Institute, Re: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida, Administrative Complaint filed with HHS OCR (May 28, 2014), https://healthlaw.org/resource/nhelp-and-the-aids-institute-complaint-to-hhs-re-hiv-aids-discrimination-by-fl/.

practice the ACA was designed to prevent."[13] PhRMA, Coverage Without Access: An Analysis of Exchange Plan Benefits for Certain Medicines, http://www.phrma.org/affordable-care-act/coverage-without-access-an-analysis-of-exchange-plan-benefits-for-certain-medicines#sthash.o0bB3Xh0.pdf

The key advantage to an outlier analysis of prescription drug coverage or other plan benefits is that it provides an apples-to-apples comparison across plans. However, an outlier analysis has a significant limitation – it fails to detect unlawful discriminatory practices that are pervasive.[14] As HHS noted, "the mere fact that a benefit design is similar to other benefit designs offered in a market does not establish that the benefit design is non-discriminatory." 2017 Letter to Issuers, at 47. Despite its implicit limitations, HHS concluded that examining plan benefits for outliers for cost sharing and other features can be effective in identifying some types of discriminatory benefit design.

[13] *See also* John V. Jacobi et al., Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring, Targeted Enforcement and Regulatory Reform, 120 Penn. St. L. Rev. 109, 174 (2015) (discussing the need for continued assessment of plans and forms of discrimination).

[14] Researchers at the Harvard School of Public Health found that the practice of placing HIV drugs in the highest cost sharing tier, which they called "adverse tiering," to be widespread. Douglas B. Jacobs & Benjamin D. Sommers, MD, PhD, Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace, N Engl J Med 2015; 372:399-402 (Jan. 29, 2015).

### 3. Clinical guidelines analysis

In the Letter to Issuers for 2016, HHS describes the analytical framework it will use to evaluate features of plan benefit design using clinical guidelines HHS announces it will review available treatment, "recommended by nationally-recognized clinical guidelines" for four selected medical conditions "to ensure that issuers are offering a sufficient number and type of drugs needed to effectively treat these conditions, and on some first line drugs, are not restricting access through ***lack of coverage*** and inappropriate use of utilization management techniques." 2016 Letter to Issuers, at 41 (emphasis added). In the relevant discussion in the proposed rule, HHS comments "Issuers are expected to impose limitations and exclusions based on clinical guidelines and medical evidence." 2016 Letter to Issuers at 38; s*ee also* BPP Rule, 80 Fed. Reg. 10822. HHS also describes the analysis of plan benefits and estimated out-of-pocket costs associated with standard treatment protocols for specific medical conditions using nationally-recognized clinical guidelines. 2016 Letter to Issuers at 38.

HIV advocates raised the issue of arbitrary coverage exclusions when they complained that many Qualified Health Plans (QHPs) offered through the

Marketplaces failed to cover single tablet therapy for HIV.[15] 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.[16] HHS concluded that plans that cover some treatments, but fail to cover the standard of care for HIV treatment, are discriminatory. The conclusion underscores how plans can meet the minimum coverage standard for Essential Health Benefits (EHB), and still run afoul of nondiscrimination protections. See 45 C.F.R. § 156.122(a)(1), requiring a minimum of one drug per United States Pharmacopeia class and category or the state's EHB benchmark plan, whichever is greater.[17]

A standard of care analysis has distinct advantages by evaluating coverage exclusions as compared with established treatment guidelines. The trial court erred by failing to consider the standard of care test when evaluating the exclusion of

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[15] *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.

[16] 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 Oct. 25, 2018) (last accessed Jan. 27. 2019). https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.

[17] *See also* 45 C.F.R. § 156.125, which specifies that "[a]n issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions."

hearing aids and related outpatient services. Experts in hearing loss reasonably conclude that hearing aids are the standard of care for many people experiencing hearing loss. The exclusion of such services, like the failure to cover single tablet therapy in the treatment of HIV, is discriminatory and should end.

### B. Washington failed to evaluate whether the non-cochlear hearing treatment exclusion was discriminatory benefit design

The process of plan review for benefit design in the State of Washington illustrates why rigorous scrutiny is necessary to enforce the ACA's protections. Section 1557 does not allow for discriminatory benefit design by ACA-regulated insurers, even if the benefit limitation that is discriminatory is allowed as part of the state's EHB benchmark plan. For example, in Washington, regulations permitted a blanket exclusion of all coverage for transgender health services. WAC 284-43-5640 (3)(b)(iii)(C). After the state EHB rule was promulgated, the Washington Office of the Insurance Commissioner (OIC) concluded that medically necessary services for transgender individuals must be covered to the same extent that those services are covered for non-transgender individuals enrolled in the same plan. *See* OIC letter to insurance carriers in Washington State (June 25, 2014), available at https://www.insurance.wa.gov/sites/default/files/documents/gender-identity-discrimination-letter.pdf (last visited 1/27/19). The Commissioner also charged the Kaiser Foundation Health Plan of Washington with violating Section

1557, resulting in a settlement agreement to replace the plan's blanket exclusion of all coverage for a particular transgender health procedure with individualized medical necessity reviews when the treatment is recommended by a qualified provider.[18] *See* Wash. Office Ins. Comm'r, *Kreidler prompts Kaiser to write new policy to treat transgender women fairly* (Aug. 1, 2018), available at https://www.insurance.wa.gov/news/kreidler-prompts-kaiser-write-new-policy-treat-transgender-women-fairly. As a result of the settlement, Kaiser is prohibited from applying a blanket exclusion to requests for coverage of this procedure to treat gender dysphoria. Instead, it must perform individualized medical necessity reviews when the treatment is recommended by a qualified medical provider. Complaint Resolution Agreement, Order 18-0175 effective July 30, 2018, available at

[18] Kaiser's coverage policy allowed for coverage of chest reconstruction for transgender men and cisgender women who have had a mastectomy but did not allow the same coverage to transgender women. As a result of the settlement, Kaiser cannot apply a blanket exclusion to requests for coverage of this procedure to treat gender dysphoria. Instead, it must perform individualized medical necessity reviews when the treatment is recommended by a qualified medical provider. *See* Complaint Resolution Agreement, Order 18-0175 effective July 30, 2018, available at https://fortress.wa.gov/oic/consumertoolkit/Orders/OrderProfile.aspx?OrderNumber=18-0175 (last visited 1/27/19). In both situations—the blanket EHB exclusion and the exclusion of chest surgery for transgender women—the Commissioner found that blanket exclusions of transgender health care are discriminatory.

https://fortress.wa.gov/oic/consumertoolkit/Orders/OrderProfile.aspx?OrderNumber=18-0175

Similarly, Washington's EHB benchmark permits insurers to apply a blanket exclusion of non-cochlear hearing treatment. The Washington EHB standards include cochlear hearing treatment within the Benchmark plan as both "ambulatory patient services" and "rehabilitative services." WAC §§ 284-43-5640(1)(b)(vii) & (7)(b)(1). The services for hearing loss excluded in this case should be covered similarly as they are medical services generally covered as inpatient treatment, surgery, outpatient office visits, and durable medical equipment and are not covered solely because of the exclusion for hearing loss. State health advocacy groups, including *amicus* NoHLA, identified this blanket exclusion as discriminatory during the state EHB rulemaking process as they also commented on the transgender exclusion, but the Commissioner did not respond directly to these concerns. To the extent there was a response on this hearing loss exclusion, it did not address whether the exclusion was discriminatory, but instead focused on the need for a "sunrise review" by the Washington Department of Health before including the benefit.[19] *See* OIC Concise Explanatory Statement, EHB, R 2015 02,

[19] Under a sunrise review, the Washington legislature has discretion to request review of all mandated health insurance benefits, with the intent that all mandated benefits show a favorable cost-benefit ratio. *See* RCW 48.47.03 and RCW 48.47.005.

at 21 (hearing loss exclusion); 16, 23, 25 (transgender exclusion), https://www.insurance.wa.gov/sites/default/files/documents/2015-02-ces.pdf. Importantly, the Commissioner never addressed whether the exclusion was discriminatory in the CES and the concern regarding the sunrise review was unfounded as a previous review had addressed the issue.[20] Moreover, the lack of action by the Commissioner is not evidence of the legality of the exclusion. *See O.S.T. v. Regence BlueShield*, 181 Wn.2d 691, 700 n.9, 335 P.3d 416, 421 (2014).

[20] Washington insurers already cover the most expensive form of hearing treatment, cochlear implants, which can cost approximately $100,000 including pre-op testing, surgery, and the cost of the implant. *See* AARP, Do You Need an Implanted Hearing Device?, https://www.aarp.org/health/conditions-treatments/info-2015/implanted-hearing-devices.html (last visited 1/27/19). In the sunrise review conducted in 2005, the Washington Department of Health commented that the estimates on cost for adding non-cochlear hearing treatment ranged from as low as a .03-.06 % premium increase for a benefit with limitations, to 1.1-1.3% premium increase if the benefit were unlimited. Hearing Aids Mandated Benefits Sunrise Review, Wash. State Dept. of Health (Jan. 2005) at 8. More recently, the Washington Legislature added an unlimited benefit for public employees both in its Kaiser fully insured plan and the public employee self-funded plan, as well as for adult Medicaid enrollees. *See* Fiscal Note for ESSB 5179, pp. 2-3, found at https://fortress.wa.gov/FNSPublicSearch/GetPDF?packageID=52158 (last visited 1/27/19). The cost of adding hearing aid coverage in the self-funded plan was relatively modest – just $50 for hearing tests, $3,000 for hearing aids, and $225 for the cost of hearing aid repairs. *Id.*, p. 2. In addition, most insurers have covered cochlear implants since 2004. *See* U.S. Food & Drug Admin., Medical Devices FAQ, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062866.htm#iq (last visited 1/27/19).

An exclusion for medically necessary treatment for individuals with disabilities, in this case hearing loss, must be therefore be closely examined for disability discrimination. This analysis must take into consideration the changes the ACA created in health insurance programs, the examples of discrimination that have been corrected by the ACA, and the guidance provided for examining claims of discrimination from the text of the statute, the regulations, and the sub-regulatory guidance offered by HHS.

## CONCLUSION

Congress crafted the ACA to address the failure of existing laws to provide broad access to health care coverage and protect from discrimination in that coverage. Section 1557 explicitly prohibits discrimination and also protect the rights found throughout the ACA to access and receive meaningful health coverage regardless of race, sex, age, health status, and disability. Thus, as courts evaluate claims of discrimination, they must consider the array of protections included in the ACA, how the Act's provisions prohibit discrimination that was previously permitted under law, and the new approaches the Act prescribes to eliminate discrimination in health insurance.

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## CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I certify that the foregoing brief complies with the requirements of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5), and that the total number of words in this brief is 6,415 according to the count of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

Date: January 29, 2019

/s/ Sarah Somers
Sarah Somers

## CERTIFICATE OF SERVICE

I certify that on January 29, 2019, I electronically filed the forgoing brief with the Clerk of the Court by using the CM/ECF system.

Date: January 29, 2019

/s/ Sarah Somers
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