October 3, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Section 1557 of the Patient Protection and Affordable Care Act (ACA), *Docket ID HHS-OS-2022-0012*

Dear Secretary Becerra:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the Department of Health and Human Services (HHS) proposed rule for Section 1557 of the ACA, *Docket ID: HHS-OS-2022-0012*.

Ensuring Section 1557 of the ACA is properly enforced is essential to equitable access to care. With that in mind, Aimed Alliance supports **(1) clarifying that discrimination can occur through benefit designs and excessive benefit utilization management; (2) prohibiting discrimination in value assessments; (3) clarifying the scope of liability for third-party companies initiating or managing discriminatory plan designs; and (4) ensuring non-discriminatory access to telehealth services.**

I. Discrimination Through Benefit Design and Excessive Utilization Management

In Section 92.207(c) of the proposed rule, HHS clarifies that excessive use or administration of benefit utilization management tools that target particular conditions, which could be considered a disability, could violate Section 1557.[1]

Benefit utilization practices without appropriate guardrails can harm patients by damaging the patient-provider relationship and increasing the likelihood of patients experiencing negative long-term health outcomes. For instance, one survey found that step-therapy, which requires patients to try-and-fail on alternative medications before the originally prescribed treatment is covered, created additional out-of-pocket costs for chronically ill patients, and decreased treatment adherence.[2]

Therefore, Aimed Alliance strongly supports this clarification and urges HHS to clarify what is considered "excessive" and provide examples of what type of benefit utilization might meet the criteria for excessive. For instance, one health plan policy requires enrollees to follow a

[1] Federal Register Vol. 87, No. 149, Thursday, August 4, 2022, p. 47874.
[2] Jennifer Snow, Madelaine Feldman, Jenna Kappel, *The Impact of Step-Therapy Policies on Patients,* https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/impact-of-step-therapy-on-patients_final_1019.pdf?la=en&hash=A7BB3FA4DAC189D9240CF8B724B435A8942E91DF

Aimed Alliance
1455 Pennsylvania Ave · Washington, DC 20004 · 202-349-4089 · www.aimedalliance.org · @aimedalliance

seven-step step-therapy process, including stepping through off-label medications, in order to access a Food and Drug Administration (FDA) approved medication for tardive-dyskinesia.[3] The proposed rule does not adequately clarify whether this type of policy would be considered a violation of Section 1557. Thus, Aimed Alliance requests that HHS provide additional examples, like it did for discrimination based on age in the 2023 Notice of Benefit and Payment Parameters,[4] to ensure covered entities, enrollees, health care professionals, and non-profits can identify when a benefit utilization practice may be considered "excessive".

II. Discrimination Inherent in Value Assessments

HHS's proposed rule clarifies that value assessments may be discriminatory if the assessment penalizes an individual or group based on their race, color, national origin, sex, age, or disability. Moreover, HHS has also requested examples of value assessments that may be discriminatory.

Aimed Alliance reiterates its long-standing position against the use of discriminatory quality adjusted life year (QALY) value assessments. QALYs essentially place a price tag on a human life that simply reflects a diagnosis, and considers people with chronic, rare, and debilitating conditions as worth less than individuals with more common conditions. QALYs value treatments on their ability to provide patients with near "perfect health".[5] For individuals with chronic conditions and disabilities, this approach makes it more difficult for them to access medications because treatments developed to improve their condition may not raise them to a level of "healthy" similar to their non-disabled peers.[6] As a result, these individuals' treatments are deemed to yield less value and may not be covered by their health plan. Therefore, Aimed Alliance strongly encourages HHS to prohibit QALYs based on their inherent discriminatory effects. Furthermore, Aimed Alliance urges HHS to create clear guidelines for when a value assessment policy will be considered discriminatory.

III. Responsibility of Third-Party Companies for Initiating Discriminatory Plan Designs

Previously in HHS's 2016 Section 1557 Rule, HHS stated that third party administrators were not liable for administering discriminatory plan designs of self-insured group health plans, as the third-party administrators had no control over the plan's design. In the current proposed rule, HHS has clarified that a third-party administrator can be held liable for a discriminatory plan design where the third-party administrator is responsible for the development of the group health plan document or other policy documents that are adopted by the self-insured plan; or

---

[3] *Molina Health Care,* https://www.molinahealthcare.com/providers/tx/PDF/Marketplace/Pharmacy/RXSC2019112.pdf
[4] HHS, *Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2023,* https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023
[5] William S. Smith, *The U.S. shouldn't use the "QALY" in drug cost-effectiveness reviews,* https://www.statnews.com/2019/02/22/qaly-drug-effectiveness-reviews/
[6] *Id.*

Aimed Alliance
1455 Pennsylvania Ave · Washington, DC 20004 · 202-349-4089 · www.aimedalliance.org · @aimedalliance

when the discriminatory plan terms originated with the third-party administrator rather than the plan sponsor.[7]

Aimed Alliance supports HHS clarifying that third-party administrators can be held liable for helping a self-insured plan adopt a discriminatory plan design. We urge HHS to further clarify that, in addition to third-party administrators, third-party companies that partner with health plans to administer discriminatory plans can also be held liable for discrimination under Section 1557.

A. The Growing Trend of Third-Party Companies Managing Specialty Medication Benefits

Third-party companies have begun contracting with health plans to administer the plans' specialty medication benefits. Under these programs, plans state that specialty medications for certain conditions will be required to go through a third-party program to receive their treatments. For instance, one university that has adopted this program stated "the [third-party program] includes 80+ non-essential health benefit medications covering conditions such as ***hepatitis C (Hep C), multiple sclerosis (MS), psoriasis, inflammatory bowel disease (IBD), rheumatoid arthritis (RA), cancer and others.***"[8] Under these programs, enrollees with the listed conditions are informed they must enroll in the third-party specialty benefits program in order to access their medication. If enrollees, enroll in the program they receive their medication for a low copay of $0-$5.[9] However, if enrollees wish not to enroll in the program, they are responsible for a 30 percent to 70 percent coinsurance that does not count towards their deductible or annual out-of-pocket limit. Thus, enrollees essentially are given no option but to enroll in these third-party programs. Once enrolled, these programs accept copay assistance from patient assistance programs on behalf of the enrollee but do not count the assistance towards the enrollee's deductible or annual out-of-pocket limit. This results in enrollees with chronic conditions paying substantially more out-of-pocket to reach their cost-sharing requirements than non-chronically ill enrollees who do not require specialty medications. Overall, these programs are treating patients with chronic conditions adversely based on their health condition.

These programs have become increasingly popular amongst employers, with one survey finding that over 30 percent of commercial insurance plans were exploring using a third-party program to manage specialty benefits.[10]

---

[7] Proposed Rule, *Nondiscrimination in Health Programs and Activities*, https://www.federalregister.gov/documents/2022/08/04/2022-16217/nondiscrimination-in-health-programs-and-activities.
[8] Iona University, *SaveonSP – Variable copayments for certain specialty pharmacy medications,* https://www.iona.edu/offices/human-resources/employee-benefits/health-insurance/saveonsp-variable-copayments-certain.
[9] SaveOnSP, *FAQ,* https://www.saveonsp.com/employers/; PrudentRx, *Frequently Asked Questions,* https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf.
[10] Adam Fein, *The Shady Business of Specialty Carve-Outs,* https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html.

B. These Programs Must Be Held Accountable for Developing Discriminatory Plan Designs

Currently, third-party specialty benefits programs are convincing plans to adopt discriminatory plan designs and attempting to scapegoat all accountability on the plan. Recently, Johnson & Johnson filed a lawsuit against SaveOnSP over its third-party specialty benefits program.[11] In response to Johnson & Johnson's complaint, SaveOnSP filed a motion to dismiss.[12] In its motion to dismiss, SaveOnSP states that it "advises self-funded plan sponsors on how to structure their benefit design . . ."[13] In attempting to avoid liability for creating this plan design, SaveOnSP argues "SaveOn does not set these benefit terms—the plan sponsors do."[14] SaveOnSP appears to claim that its conduct is permissible under current (pre-rulemaking) HHS rules, under which SaveOnSP apparently believes it cannot be held responsible for convincing plans to adopt a discriminatory plan design because it is the plan that sets the benefits, not SaveOnSP. All the while, SaveOnSP gives the plan the idea, helps the plan implement the idea, and helps monitor and manage the program.[15]

While this case is still being litigated in the U.S. District Court for the District of New Jersey, the argument SaveOnSP is making is applicable to the wider net of third-party specialty benefits programs. Allowing third-party programs to avoid accountability for creating and helping implement a discriminatory program by pointing to the health plan as a scapegoat, would be inconsistent with the intent of the current proposed rule, which aims to ensure any party that attempts to discriminate in violation of Section 1557 is held responsible for its conduct.

Therefore, to prevent third parties from promoting or managing discriminatory specialty medication programs, Aimed Alliance respectfully requests that HHS expressly state that under Section 1557, third party companies may be held liable when discriminatory plan terms originate with, or are managed by, the third-party company.

IV. Telehealth Expansion Must Include Ensuring Accessible Telehealth Services

Currently, the proposed rule clarifies that information and communication technology, such as telehealth, must be provided in an accessible manner for individuals with disabilities, unless doing so would create an undue financial or administrative burden for the health program or activity. The proposed rule would also prohibit discrimination in the delivery of telehealth services and recognizes the need for telehealth services to be more widely accessible. For instance, the proposed rule recognizes that telehealth services are often inaccessible for deaf individuals, individuals who are blind, or have cognitive disabilities because these platforms

---

[11] Johnson & Johnson, *Complaint May 4, 2022,* https://www.drugchannelsinstitute.com/files/22-cv-02632.pdf.
[12] SaveOnSP, *Memorandum of Law in Support of Defendant's Motion to Dismiss,* July 15, 2022 (available on PACER), https://aimedalliance.org/wp-content/uploads/2022/09/SaveOnSP-Motion-to-Dismiss.pdf.
[13] *Id.* at p. 6.
[14] *Id.* at p. 7.
[15] *Id.* at p. 29.

Aimed Alliance
1455 Pennsylvania Ave · Washington, DC 20004 · 202-349-4089 · www.aimedalliance.org · @aimedalliance

often do not use real-time captioning, interpreters, or supportive decision makers, and are incompatible with screen readers.

Aimed Alliance encourages HHS to set a minimum standard for what is considered accessible information and communication technology, to ensure there is a baseline of requirements providers must comply with. This minimum will also ensure providers have a guiding standard to use when revising policies and procedures. Additionally, Aimed Alliance strongly encourages HHS to develop clear resources for consumers with disabilities to inform them on the type of accessibility requirements that should be followed when using telehealth services.

V. Conclusion

Thank you for providing us with the opportunity to comment on the Proposed 1557 Rule. Please contact us at policy@aimedalliance.org if you would like to discuss any of the comments herein.

Sincerely,

Ashira Vantrees
Counsel

Aimed Alliance
1455 Pennsylvania Ave · Washington, DC 20004 · 202-349-4089 · www.aimedalliance.org · @aimedalliance