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October 3rd, 2022

VIA ELECTRONIC FILING – *http://www.regulations.gov*
The Honorable Xavier Becerra
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Nondiscrimination in Health Programs and Activities; Notice of Proposed Rulemaking; RIN: 0945-AA17, Docket ID: HHS-OS-2022-0012

Dear Secretary Becerra:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the Nondiscrimination in Health Programs and Activities proposed rule published by the U.S. Department of Health and Human Services (HHS), also referred to as "Department" below.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

Through Section 1557, the Affordable Care Act (ACA) recognizes the importance of preventing discrimination against individuals in specified health care programs and activities on the grounds of race, color, national origin, sex, age, or disability. Section 1557's nondiscrimination protections are particularly important in the context of prescription drugs and vaccines, given the critical role that medicines play in modern health care. Comprehensive prescription drug coverage—whether for medicines covered by the outpatient pharmacy benefit or as part of the medical benefit, such as drugs administered incident to a physician's service—plays an important role in preventing, treating, and curing serious and chronic health conditions, as well as improving quality of life and reducing other health care costs. The need for comprehensive and nondiscriminatory drug coverage is often most significant among individuals with disabilities and those in underserved communities, making Section 1557's protections critical.

PhRMA supports HHS's efforts to further define and enforce nondiscrimination principles in federally funded and administered health care programs and activities through this proposed rule. In the proposed rule, HHS recognizes that discrimination in health programs and activities takes various forms and that a comprehensive set of rules and standards is needed in order to adequately protect individuals, as required by Section 1557 and other provisions in the ACA. This proposed rule has the potential to be an important step forward because at present, health plans are not held to standards that are consistent with the nondiscrimination provisions in

[1] 87 Fed. Reg. 47824 (Aug. 4, 2022); RIN: 0945-AA17

the ACA. Formulary design—particularly the practice of placing all medicines for certain conditions on the highest cost sharing tier—has been a primary area of concern regarding potentially discriminatory benefit designs.[2] Although under the ACA, Marketplace plan benefit designs may not be constructed in ways that "have the effect of discouraging the enrollment in such plan[s] by individuals with significant health needs,"[3] these plans have designed benefits that have this precise effect, with particularly negative consequences for persons of color or with disabilities. PhRMA encourages HHS to finalize the proposals in this rule that protect patients from these practices, but to also go further in collecting data and fleshing out additional examples to ensure that health insurance coverage cannot be designed to discriminate against individuals with disabilities and living with chronic conditions who utilize certain medicines or rely on copay assistance, for example.

PhRMA has the following comments, discussed in greater detail below:

- **Broadly apply nondiscrimination provisions.** PhRMA applauds the proposed rule's broad application of Section 1557, including, to the extent they are considered recipients of federal financial assistance, health insurance issuers, third party administrators, pharmacy benefit managers, and sponsors of group health plans. We further support the inclusion of the Department itself, Medicare Part B providers, issuers of health-related coverage (such as short-term limited duration or excepted benefits plans), and group health plans.
- **Promote health equity to close gaps in medication access.** We support the Administration's spotlight on the pervasive inequities that exist in our health care system, including in access to medications. In order to ensure and promote health equity, we urge HHS to review systematically its own rules and regulations governing the programs it oversees that may perpetuate inequalities for vulnerable people living with chronic conditions. We also encourage the Department to create a data collection framework that gives the federal government the information needed to document and ameliorate potentially discriminatory activity and outcomes.
- **Prevent discriminatory benefit designs.** The proposed rule states clearly that benefit designs cannot be discriminatory. We urge HHS to flesh out examples of discrimination in the final rule and consider the ways in which discrimination might occur through formulary design, adverse tiering, accumulator adjustment and copay maximizer programs, alternative funding programs, or any other scheme for health plans or third parties to divert or profit from patient assistance.

[2] D. Jacobs and R. Restuccia, "Ensuring A Discrimination-Free Health Insurance System," Health Affairs Blog, June 11, 2015, https://www.healthaffairs.org/do/10.1377/forefront.20150611.048374.
[3] ACA § 1311(c)(1)(A).

- **Recognize where coverage denials become discriminatory.** The proposed rule recognizes that covered entities might have grounds for certain coverage decisions, but should be clear that excessive use of utilization management tools could be discriminatory.
- **Ensure network adequacy.** The rule, when final, should take further steps to incorporate the development of provider networks. In particular, the Department should discuss how discriminatory pharmacy contracting inhibits patient access to certain medications.
- **Scrutinize the use of clinical algorithms in medical decision-making.** We support the proposed rule's emphasis on decisions being made based on clinical judgment, rather than based on algorithms alone, and we encourage the Department to extend this provision to include all automated decision-making tools or models.
- **Ensure that nondiscrimination protections are enforced.** We support the enforcement mechanisms outlined in the rule, including the Department's authority to demand remedial action or suspend or terminate funds, in addition to the role private parties will play in monitoring and enforcement.

Part 92, Nondiscrimination in Health Programs and Activities

Subpart A – General Provisions

In keeping with congressional intent, the proposed rule broadly applies Section 1557 to prohibit discrimination on the basis of race, color, national origin, sex, age, or disability in any health program or activity that, in any part, directly or indirectly accepts federal financial assistance or is administered by HHS or a Title I (of the ACA) entity.

Broad Application of Section 1557

We support the expansive definition of the law's applicability and the definition of "health program or activity" that, notably, removes the limitation the current regulations impose on Section 1557's application to health insurance issuers. As noted by HHS, this approach is consistent with the intent of Section 1557 to apply the nondiscrimination requirements to health insurance and other health-related coverage where an entity receives federal financial assistance. The proposed rule's broad scope also captures Medicaid managed care organizations and, to the extent they are considered recipients of federal financial assistance, pharmacy benefit managers (PBMs), sponsors of group health plans, and third-party administrators.[4] In particular, this inclusive definition appropriately incorporates entities that design and provide private health insurance. These protections can help identify and remedy potentially discriminatory policies and practices that the sponsors of group health plans and their service providers (including PBMs) implement – including formulary exclusions, adverse tiering, use of accumulator adjustment

[4] *See* 87 Fed. Reg. at 47869 n.435.

programs and/or copay maximizers, and step therapy – that may adversely impact enrollees with significant health care needs.

In defining federal financial assistance in § 92.4, the Department proposes for the first time to treat Medicare Part B funds as federal financial assistance, thereby applying nondiscrimination protections to providers who accept those funds. While the government's compensation for services provided is not itself federal financial assistance, the Department reasons that, as with Part A, providers receive a benefit from Part B as a reliable source of payment for services or providers that beneficiaries otherwise would not have been able to afford. Medicare Part B providers are appropriately included within the broad purview of the Section 1557 definition of covered entities.

The 2016 final rule implementing ACA section 1557 categorically covered group health plans under the definition of a health program or activity,[5] and PhRMA urges HHS to explicitly include group health plans in its proposed definition as a covered entity if a group health plan receives federal financial assistance from the Department. This approach is consistent with the ACA's intent to protect all individuals from discrimination in health insurance and health-related coverage and acknowledges the key role that the private sector plays in ensuring people have access to care as noted by HHS.[6] In response to the Department's request on the circumstances under which a group health plan might receive funds that could be considered federal financial assistance, we suggest receipt of Medicare Part D payments to be included as an example in the final rule. As noted in the preamble to the 2016 rule, many group health plans receive federal Medicare Part D payments.[7] This should properly be considered federal financial assistance, and indicating that example in the final rule would give group health plans needed clarity on when the provision applies.

Last, we understand HHS seeks comments as to whether the entirety of operations of a State Medicaid program, a Children's Health Insurance Program, and the Basic Health Program should explicitly be referenced in final regulatory language for Section 1557. PhRMA supports the explicit reference of all named programs in the final rule for completeness and for clarity for all stakeholders. In particular, we support the reference to the Basic Health Program. While only two States (New York and Minnesota) have implemented the Basic Health program, at least two additional States (Kentucky and Oregon) are considering implementing this program for people ineligible for Medicaid. In light of the upcoming end of the COVID-19 public health emergency in which millions of Americans are expected to be disenrolled from Medicaid, more States may consider implementing the Basic Health Program as a means of maintaining access to coverage and care for their residents. The upcoming transition and the interest of States in expanding access makes it vital that this program (as well as Medicaid and CHIP) is discussed explicitly in reference to ensuring nondiscrimination and we urge HHS to include references to these programs in the final rule.

Promoting Equitable Cures by Applying Section 1557 to All Departments Programs

[5] 45 C.F.R. § 92.4 (2016).
[6] *See* 87 Fed. Reg. 47824 at 47845.
[7] 81 Fed. Reg. 31376 at 31438 n.273 (May 18, 2016).

The inclusion of the National Institutes of Health and the Centers for Medicare & Medicaid Services, and all programs administered by the Department, in nondiscrimination protections can advance equitable health. Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and that all people should have equitable access to treatment, without regard to race, color, national origin, sex, age, or disability.[8] As such, we applaud the Administration's demonstrated commitment to the advancement of health equity in this proposed rule and through other actions, and urge the Administration to review systematically its own rules and regulations governing the programs it oversees that may perpetuate inequalities for vulnerable people with chronic conditions.

As underscored in the preamble, pervasive health disparities persist across many dimensions. For example, researchers have found that there are some diseases and conditions that affect racial and ethnic communities at a higher rate than the average population, such as Alzheimer's disease, certain cancers, chronic lung conditions, type 2 diabetes, heart conditions, HIV infection, liver disease, obesity, sickle cell disease and stroke.[9] In 2021, there were 829 medicines in development by biopharmaceutical research companies to address these diseases, all of which are in human clinical trials or awaiting review by the FDA.[10]

We look forward to working with HHS to achieve their equity goals. PhRMA is committed to closing gaps in medication access to improve the health and well-being of all Americans. We are concerned by the numerous studies demonstrating that certain racially or ethnically diverse populations have lower medication adherence than their white counterparts.[11,12,13] Evidence has shown that the downstream consequences of such medication

[8] PhRMA, "Building a Better Health Care System: PhRMA's Patient-Centered Agenda," https://phrma.org/report/Building-a-Better-Health-Care-System-PhRMAs-Patient-Centered-Agenda.
[9] PhRMA's Medicines in Development. 2021 Report: Health Equity. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/MID-Reports/MID-Health-Equity-2021-Report.pdf.
[10] Number of medicines obtained through public government and industry sources, and the Springer "AdisInsight" database; current as of June 8, 2021.
[11] Mehta KM, Yin M, Resendez C, Yaffe K. Ethnic differences in acetylcholinesterase inhibitor use for Alzheimer disease. Neurology. 2005 Jul 12;65(1):159-62. doi: 10.1212/01.wnl.0000167545.38161.48. PMID: 16009909; PMCID: PMC2830864.
[12] Lauffenburger JC, Robinson JG, Oramasionwu C, Fang G. Racial/ethnic and gender gaps in the use of and adherence to evidence-based preventive therapies among elderly Medicare part D beneficiaries after acute myocardial infarction. Circulation. 2014; 129:754–763.
[13] Schmittdiel JA, Steiner JF, Adams AS, et al. Diabetes care and outcomes for American Indians and Alaska natives in commercial integrated delivery systems: a SUrveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM) Study. BMJ Open Diabetes Res Care. 2014;2(1):e000043. Published 2014 Nov 17. doi:10.1136/bmjdrc-2014-000043.

nonadherence includes increased health care costs,[14] poor health outcomes,[15,16] and increased risk of mortality.[17] In an effort to drive meaningful dialogue and potential solutions to these and other systemic challenges, PhRMA released a patient-centered agenda, "Building a Better Health Care System," which demonstrates the biopharmaceutical industry's commitment to working with all stakeholders to deliver a stronger, more resilient, affordable and equitable health care system for all.[18] We encourage HHS to put equity considerations at the center of health programs and activities throughout the Department and its agencies.

Data Collection to Identify and Target Discriminatory Impacts

The preamble to the proposed rule requests comment on whether (and which) covered entities should be required to collect demographic data and on current practices around data collection. While standards exist for the collection and reporting of race, ethnicity, language, sex, and disability data in all publicly funded national administrative files and health surveys, these standards do not apply to many other reporting entities at the Federal, State, and local levels.[19] Additionally, current federal standards for race/ethnicity data are not sufficiently granular to reflect diversity – and therefore health disparities – for smaller underrepresented communities within broad categories of race and ethnicity.[20] PhRMA suggests that the Department consider requiring some or all covered entities to collect standardized, granular data on ethnically and otherwise diverse populations, so that data representing diversity across a broad range of cultures, backgrounds and lived experiences can be synthesized and to determine whether the discrimination persists.[21,22]

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[14] Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care. 2005 Jun;43(6):521-30. doi: 10.1097/01.mlr.0000163641.86870.af. PMID: 15908846.

[15] Bansilal S, Castellano JM, Garrido E, Wei HG, Freeman A, Spettell C, Garcia-Alonso F, Lizano I, Arnold RJ, Rajda J, Steinberg G, Fuster V. Assessing the Impact of Medication Adherence on Long-Term Cardiovascular Outcomes. J Am Coll Cardiol. 2016 Aug 23;68(8):789-801. doi: 10.1016/j.jacc.2016.06.005. PMID: 27539170.

[16] Choudhry NK, Glynn RJ, Avorn J, Lee JL, Brennan TA, Reisman L, Toscano M, Levin R, Matlin OS, Antman EM, Shrank WH. Untangling the relationship between medication adherence and post-myocardial infarction outcomes: medication adherence and clinical outcomes. Am Heart J. 2014 Jan;167(1):51-58.e5. doi: 10.1016/j.ahj.2013.09.014. Epub 2013 Oct 17. PMID: 24332142.

[17] Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. Diabetes Care. 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.

[18] PhRMA, "Building a Better Health Care System: PhRMA's Patient-Centered Agenda." https://phrma.org/report/Building-a-Better-Health-Care-System-PhRMAs-Patient-Centered-Agenda.

[19] Office of Management and Budget (1997). Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf.

[20] Ibid.

[21] The Initiative on Asian Americans and Pacific Islanders. The White House. Available at: https://obamawhitehouse.archives.gov/administration/eop/aapi/data/data.

[22] U.S. Department of Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language and Disability Status. Department of Health and Human Services. October 31, 2011. https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status#IV.

Although PhRMA strongly supports more robust collection of data, we recognize that increased surveillance and monitoring is not without potential harms to communities. For example, many disadvantaged communities have legitimate fears of sharing personal information due to negative potential consequences.[23] The collection of data should serve to improve health care programs for diverse communities, not provide a means for harmful discrimination. We recommend that the Department consult engagement experts to test and implement safeguards, ensuring that personally identifiable information remains protected throughout the process. In addition, we recommend that the Department engage with experts to test and pilot strategies to mitigate against use of patient information that can potentially negatively impact patient access or care. For example, as discussed elsewhere in the rule, some artificial intelligence algorithms rely on demographic information to determine treatment regimens. There is evidence that these algorithms can lead to bias in treatment decisions if not properly developed and tested.[24]

In addition, we recommend that the Department continue to test and pilot the level of granularity within each data element, similar to OMB's efforts to continue to refine race and ethnicity measurement.[25] Refinement of the granularity of data elements will help to ensure that pressing health disparities are not overlooked due to the aggregation of data elements. Because populations may experience more than one source of disadvantage at a time, efforts to advance demographic data collection should also seek to collect information on social factors and their intersection with demographic information.[26] Intersectionality, a term coined by legal scholar Kimberlé Crenshaw, describes how intersecting systems of oppression (e.g., racism and sexism) have multiplicative impacts on an individual's life experiences.[27] Using a framework such as intersectionality to guide better data collection can reduce disparities in quality of care at intersections that influence health outcomes and patient experiences.

Any demographic data collected should be in a format that both allows assessment of covered entities' participant characteristics and aggregation to inform larger understanding of the disparities that permeate the health care system. Currently, fewer than 15 percent of administrative health care transactions are fully electronic, including eligibility verification, checking on claim status, prior authorization, and clinical information submitted with claims.[28] There is an opportunity for Federal and State programs and other covered entities, such as health care practices and systems, to promote data sharing to measure the uptake of underserved

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[23] Luque JS, Soulen G, Davila CB. et al. Access to health care for uninsured Latina immigrants in South Carolina. BMC Health Serv Res 18, 310 (2018). https://doi.org/10.1186/s12913-018-3138-2

[24] "Algorithmic Bias In Health Care: A Path Forward," Health Affairs Blog, November 1, 2019. https://www.healthaffairs.org/do/10.1377/hblog20191031.373615/full/.

[25] Proposals from the Federal Interagency Working Group for Revision of the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. OMB. March 1, 2017. https://www.federalregister.gov/documents/2017/03/01/2017-03973/proposals-from-the-federal-interagency-working-group-for-revision-of-the-standards-for-maintaining.

[26] Nick G, Schloss K, Lekas HM, et al. A Social Determinants Perspective of the Intersection of Ageism, Racism, and Social Isolation During COVID-19. Behavioral Health News. Jan 1, 2021. https://behavioralhealthnews.org/a-social-determinants-perspective-of-the-intersection-of-ageism-racism-and-social-isolation-during-covid-19/.

[27] Crenshaw K. (1991). Mapping the Margins: Intersectionality, Identity Politics, and Violence against Women of Color. Stanford Law Review, 43(6), 1241-1299. doi:10.2307/1229039.

[28] CAQH, 2018 CAQH Index: A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings, 2019. https://www.caqh.org/sites/default/files/explorations/index/report/2018-index-report.pdf.

communities in Federal programs and activities and the impact of Federal programs and activities on eliminating health disparities. Further, electronic data sharing among plans could reduce burdens on providers and patients as doctors currently spend about four hours per week on administrative tasks such as addressing drug formulary issues, prior authorization requests, and clarifying claims information.[29]

Subpart C – Specific Applications to Health Programs and Activities

Nondiscrimination in health insurance coverage and other health-related coverage (§ 92.207(a))

Section 92.207(a) explicitly applies the nondiscrimination protections to entities that provide or administer health insurance coverage or other health-related coverage. PhRMA supports the application of nondiscrimination protections to health insurance carriers. In the proposed rule, HHS recognizes that discrimination in health programs and activities takes various forms and that a comprehensive set of rules and standards is needed in order to adequately protect individuals, as required by Section 1557 and other provisions in the ACA.[30] This has the potential to be an important step forward because at the present, certain health coverage is exempt from some nondiscrimination provisions in the ACA. To create the most robust and comprehensive protections, we support the application of these protections to short-term limited duration plans, excepted benefits, grandfathered plans and other forms of health coverage, including those not otherwise subject to any or all of the ACA's health insurance market reforms, when offered by recipients of federal financial assistance.

It is likewise appropriate to apply nondiscrimination provisions to other entities that design or implement pharmacy and other plan benefits (if they are recipients of federal financial assistance *or* acting on behalf of entities that are such recipients) to ensure they do not discriminate on the basis of health status, age, sex, race, ethnicity, national origin, or disability. This includes application to third party administrators (TPAs), PBMs, and related entities. The proposed rule recognizes that while TPAs are unable to change any discriminatory design features in the self-insured plans they administer, they do create group health plan documents and other policy documents that are adopted by the self-insured plan. If the discriminatory design is found, in a case-by-case investigation, to originate with the TPA rather than the plan sponsor, the TPA can be liable. The Department should consider a similar inquiry when stop-loss coverage has a discriminatory effect. Stop-loss policies, often sold by TPAs, use techniques such as "lasering" to target group members with high medical needs by raising attachment points based on certain criteria, such as an individual's overall medical cost or the diagnosis of a certain condition. This could mean stop-loss coverage penalizes employers when a covered individual needs intensive treatment for a disabling condition. The HHS Office for Civil Rights (OCR) should conduct case-by-case investigation to enforce section 1557 against stop-loss carriers that discriminate against individuals with disabilities.

[29] Blanchfield et al. (2010). Saving Billions of Dollars- And Physicians' Time-By Streamlining Billing Practices. Health Affairs, 29(6), 1248-1254. Retrieved from https://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0075.
[30] Other key ACA sections related to non-discrimination include ACA § 1302(b)(4)(B) and § 1311(c)(1)(A).

PBMs play a pivotal role in benefit design, including formulary design, and implementation of benefits for group health plans. The formularies that PBMs establish for plan sponsors govern which medicines are covered, the associated cost sharing required to access medicines, and any utilization management or other restrictions on their prescribing or use. In recent years, PBMs have also combined with health insurers, specialty and mail order pharmacies, and provider groups to form large vertically integrated organizations. These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, when and where they can be dispensed or administered to patients, and the amount paid out of pocket by patients.[31] PBMs should be held liable when they or their affiliates are responsible for discriminatory pharmacy benefit designs. The Department should recognize that plan sponsors often defer to the expertise of PBMs, whose actions can broadly impact individuals with disabilities and those in underserved communities. The Department's case-by-case analysis should engage in a fact-specific inquiry to assign liability appropriately to the party (the PBM or plan sponsor) responsible for the decision or allegedly discriminatory action. However, due to the opaque relationship between PBMs and plan sponsors, PhRMA is concerned that enforcement within this context may be difficult, as plan sponsors and PBMs may place the blame on each other for discriminatory features. Thus, it may be helpful for the Department to provide additional guidance clarifying who is the responsible party in certain instances to ensure that these entities appreciate their obligations under the final rule.

Specific potentially discriminatory plan design features (§ 92.207(b))

Section 92.207(b) outlines the specific protections from discrimination in health insurance coverage or other health-related coverage. The proposed rule requires that entities that provide or administer health-related insurance or other health-related coverage shall not "have or implement … benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability." PhRMA agrees that "robust enforcement" is essential to ensuring that patients receive the health services they need.[32] We further discuss PhRMA's comments on common types of plan design discrimination encountered by patients below.

Benefit Design

Especially with respect to benefit designs that discriminate on the basis of disability, PhRMA and federal courts agree that benefit design can unlawfully discriminate in violation of section 1557. [33] PhRMA notes that the statutory definition of disability applicable to section 1557 easily encompasses many chronic conditions: "a physical or mental impairment that substantially limits," among other things, "the operation of a major bodily function, including but not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions."[34] The Equal

[31] Fein, AJ. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. March 2022.
[32] 87 Fed.Reg.47824 at 47868.
[33] *See*, *e.g.*, Schmitt v. Kaiser Found. Health Plan of Wash., 965 F.3d 945 (9th Cir. 2020).
[34] 42 U.S.C. § 12102; *see* 29 U.S.C. § 705(20)(B).

Employment Opportunity Commission (EEOC), applying the same definition of disability to employment discrimination, says, "The link between particular impairments and various major bodily functions should not be difficult to identify. Because impairments, by definition, affect the functioning of body systems, they will generally affect major bodily functions. For example, cancer affects an individual's normal cell growth; diabetes affects the operation of the pancreas and also the function of the endocrine system; and Human Immunodeficiency Virus (HIV) infection affects the immune system. Likewise, sickle cell disease affects the functions of the hemic system, lymphedema affects lymphatic functions, and rheumatoid arthritis affects musculoskeletal functions."[35] HHS should make clear that benefit designs that discriminate against individuals with specific medical conditions, particularly chronic conditions, constitute unlawful disability discrimination.

HHS opts not to define benefit design in the rule. PhRMA supports the Administration's intent to interpret the term broadly to avoid being "overly prescriptive or unintentionally inconsistent" with other regulations.[36] The preamble articulates an instructive, non-exhaustive list of examples of benefit design features to which nondiscrimination provisions apply, including "coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); [and] medical management standards (including medical necessity standards)."[37] The number of medicines subject to utilization management in the private health insurance market has grown over time. A recent study by Avalere Health analyzing formularies for exchange plans and employer-sponsored health plans found that utilization management for single-source brand medicines increased for all therapeutic areas in the analysis, including conditions such as cancer, depression, rheumatoid arthritis (RA) and diabetes, between 2014 and 2020.[38] For example, use of UM for medicines used to treat RA increased more than 150% from 2014 to 2020.[39]

To protect patients from discriminatory practices across the private health insurance market, HHS should rely on other nondiscrimination provisions in the ACA when interpreting and enforcing Section 1557. For example, a Qualified Health Plan (QHP) certified by a Marketplace must "[n]ot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs."[40] In defining the Essential Health Benefits (EHB), the Secretary may not make "coverage decisions, determine reimbursement rates, establish incentive programs or design benefits in ways that discriminate against individuals because of age, disability, or expected length of life."[41] EHB must take into account health care needs of diverse segments of the population, including women, children, disabled individuals, and other groups,[42] and may not be denied to individuals

[35] Appendix to 29 C.F.R. pt. 1630.
[36] 87 Fed. Reg. 47824 at 47869.
[37] *Id.*
[38] Avalere Health. "Utilization Management Trends in the Commercial Market, 2014-2020." November 24, 2021. https://avalere.com/insights/utilization-management-trends-in-the-commercial-market-2014-2020
[39] *Id.*
[40] 45 C.F.R. § 156.225
[41] ACA § 1302(b)(4)(B).
[42] ACA § 1302(b)(4)(C).

against their wishes due to expected length of life, present or predicted disability, degree of medical dependency, or quality of life.[43] The prohibition on discriminatory benefit design also reinforces statements by the EEOC that "the use of disability-based distinctions in group health plans, including disability-specific benefit limits and exclusions, may violate the ADA [Americans with Disabilities Act]."[44] PhRMA suggests that the Department provide examples of presumptively discriminatory designs in order to protect patients and reduce discrimination in health programs and activities. As noted below, PhRMA suggests incorporating the presumptive discriminatory design examples provided in the EHB nondiscrimination policy for health plan designs.[45]

Formulary Benefit Design

Section 92.207(b)(1) of the proposed rule prohibits covered entities from "impos[ing] additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability." Formulary design has been a primary area of concern regarding potentially discriminatory benefit designs.[46] Although under the ACA, Marketplace plan benefit designs may not be constructed in ways that "have the effect of discouraging the enrollment in such plan[s] by individuals with significant health needs,"[47] health plans have designed benefit plans that have this precise effect, with particularly negative consequences for persons with disabilities. In the description of what is intended under paragraph (b)(1), the Department should add a reference to discriminatory formulary design. In addition, while State Medicaid plans may not exclude coverage of drugs under the Medicaid Drug Rebate Program (MDRP), drugs for some conditions have been subjected to unduly restricted coverage.[48]

Under current regulations, an issuer does not provide EHB if it 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."[49] This standard has proven insufficient at preventing plans from exploiting benefit design flexibilities to discriminate against patients who rely on certain prescription drugs. Specifically, plans' use of discriminatory prescription drug formularies to discourage enrollment among certain populations has been well documented over the years.[50] For many patients with chronic conditions, plans may be able to discourage

[43] ACA § 1302(b)(4)(D).
[44] U.S. Equal Employment Opportunity Commission, "Title VII / ADA: Health Insurance And Other Benefits, Re: Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market" (April 4, 2001). Section 1557 incorporates these standards from federal civil rights and nondiscrimination laws as a minimum floor, against which no "lesser standard" shall be applied. 87 Fed. Reg. 47841 (proposed rule § 92.3).
[45] *See* 87 Fed. Reg. 584 at 664-668.
[46] D. Jacobs and R. Restuccia, "Ensuring A Discrimination-Free Health Insurance System," Health Affairs Blog, June 11, 2015. https://www.healthaffairs.org/do/10.1377/forefront.20150611.048374.
[47] ACA § 1311(c)(1)(A).
[48] CMS, Medicaid Drug Rebate Program Notice, Release No. 172 (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.
[49] *See* 45 C.F.R. § 156.125(a).
[50] Douglas B. Jacobs, & Benjamin D. Sommers. "Using drugs to discriminate: adverse selection in the insurance marketplace," 372 New Eng. J. Med. 399, 401 (2015); Avalere Health. 2016 Exchange Plans Improve Access to

enrollment by certain individuals with chronic conditions and disabilities simply by not covering the medicines they need or placing them on a high cost-sharing formulary tier. However, researchers have also found that sophisticated plans have even restricted access to lower-cost brand drugs and generics when demand for those drugs attracts patients who have high health costs other than their drug utilization (for example, expected use of medical services).[51]

Another strategy payers use to discriminate against patients with complex, chronic conditions is a specialty carve-out program. Under these benefit schemes, payers transfer management of particular specialty medicines from their plan or PBM to a niche vendor that promises payers savings from specialty medication management. In fact, these vendors may employ an aggressive form of utilization management that denies life-saving mediations, including those covered under their health plan. Specialty carve-outs put "limitations or restrictions on coverage on the basis of…disability" that would be prohibited under the proposed rule.[52]

Adverse Tiering

Formulary tiering can be an appropriate tool for health plans to use when several medically appropriate treatment regimens for a condition are available to patients. The proposed rule allows covered entities to justify potentially discriminatory benefit design using accepted standards and guidelines that are based on clinical, evidence-based criteria or guidelines.[53] Adverse tiering – the practice of putting all or most drugs for a particular condition on the highest cost-sharing tier – is not a legitimate use of formulary tiering because it cannot encourage use of a preferred drug.[54] It serves only to shift costs from insurers to patients, particularly for those with chronic conditions and disabilities or to discourage patients with significant medical needs from enrolling in the first instance. For example, an analysis of exchange plans found that plans placed brand rheumatoid arthritis (RA) drugs on a specialty tier 30% of the time. Additionally, almost all exchange plans analyzed required coinsurance for medications on the specialty tier with an average coinsurance of 38%. This likely represents a significant cost burden for many patients with RA. Additionally, plans in 7 states placed all covered, branded drugs for RA or HIV on a non-preferred or specialty tier at least 50% of the time. Even in plans using copays on higher tiers, copay amounts can be substantial—of plans using copays, the average copay for drugs placed on the specialty tier ($261) is more than 3 times the average copay for drugs placed on the preferred tier ($76).[55]

Medicines Used to Treat Complex Diseases, April 2016. https://avalere.com/insights/2016-exchange-plans-improve-access-to-medicines-used-to-treat-complex-diseases.

[51] Michael Geruso, Timothy J. Layton, and Daniel Prinz. Screening in Contract Design: Evidence from the ACA Health Insurance Exchanges. Amer. Econ. J.: Econ. Pol. 11(2). May 2019. DOI: 10.1257/pol.20170014. https://www.aeaweb.org/articles?id=10.1257/pol.20170014.

[52] 87 Fed. Reg. 47824 at 47918.

[53] 87 Fed. Reg. 47824 at 47875.

[54] Placing certain formulations on the highest cost-sharing tier is also a concerning practice, as new formulations of approved drugs can offer significant advances in therapy.

[55] Unpublished Avalere analysis of tiering and cost sharing in federally-facilitated exchanges (FFE) and state-based exchanges using the federal platform (SBE-FP). September, 2022.

When all medicines to treat a condition require high-cost sharing, it can translate into higher costs for patients even when they are using generic medicines. A 2015 *New England Journal of Medicine* study found that adverse tiering in HIV coverage among federal Marketplace health plans had an average annual cost of HIV treatment (the sum of out-of-pocket costs for medicines and insurance premiums) that was more than triple the average cost faced by enrollees in plans that did not practice adverse tiering, with an estimated out-of-pocket annual cost difference of about $2,000 for those taking generic medicines.[56] Complaints to the Office for Civil Rights document these practices. For example, in Florida, four carriers offering plans on the Marketplace classified all or most generic medicines treating HIV as specialty drugs, contrary to medical standards and insurer norms.[57] Likewise, insurers in seven states allegedly did the same by treating the vast majority of HIV medications as specialty drugs that were placed on the highest cost-sharing tier, making the medicines cost-prohibitive and a de facto denial of lifesaving care.[58] Moreover, the resulting high cost sharing has the known, entirely foreseeable effect of discouraging sick patients from using needed medicines—or from enrolling in these plans in the first place. In the 2023 Notice of Benefit and Payment Parameters, HHS appropriately defined "adverse tiering" as an example of a practice that is presumptively discriminatory.[59] We recommend that adverse tiering be added to the list of examples of benefit designs to which nondiscrimination protections apply.[60]

Patient Cost-Sharing and Out-of-Pocket Costs: Accumulator Adjustment Programs, Copay Maximizers, and Alternative Funding Programs

As the Department recognizes, imposing higher cost-sharing can be an indicator of discriminatory plan design.[61] Benefit designs with higher cost sharing can discourage individuals living with disabilities and chronic conditions from enrolling into health plans with higher cost-sharing obligations as well as hinder patients from accessing their medication under their health insurance coverage because of the associated higher out-of-pocket costs. Prohibiting this practice is a key protection particularly for those living with chronic conditions who bear the brunt of paying higher out-of-pocket costs to access their life-saving medication. In addition, the ACA's annual limit on cost sharing or maximum out-of-pocket limit on EHB ensures that once patients meet this limit, their health plan fully pays for the costs of accessing EHB.[62] This is an

[56] *Supra* at 49.
[57] Administrative Complaint filed with the Office of Civil Rights by The AIDS Institute and the National Health Law Program. May 29, 2014. https://healthlaw.org/wp-content/uploads/2014/05/HIV-OCR-complaint-5-29-14-Final.pdf.
[58] Press release. "Center for Health Law and Policy Innovation of Harvard Law School Launching Groundbreaking Campaign to Enforce Health Care Rights for People Living with HIV in Seven States." September 6, 2016. https://chlpi.org/wp-content/uploads/2013/12/CHLPI_OCR-Complaint-Press-Release_web.pdf.
[59] 87 Fed. Reg. 47824 at 27304.
[60] 87 Fed. Reg. 47824 at 47869.
[61] *Id.*
[62] *See* Patient Protection and Affordable Care Act § 1302 (c)(1), 42 USC 18022 (c)(3); § 2707(b), 42 USC 300gg-6(b).

important consumer protection that the ACA applies across group health plans and group and individual coverage.[63]

Health plans, PBMs, and related entities, however, have adopted various programs whereby, contrary to established practice, they exclude from the deductible or annual limit on cost sharing the value of cost sharing paid by enrollees, but only when the enrollee uses manufacturer cost-sharing assistance to pay.

Accumulator adjustment programs penalize patients for using manufacturer cost-sharing support, and patients end up paying more out-of-pocket than is ordinarily permitted under their health plans. When accumulator adjustment programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs, increasing financial burden and health risk, especially for those with serious and chronic illnesses. Thus, accumulator adjustment programs can undermine medication adherence, which can lead to negative health outcomes for patients and increase overall health care costs.[64] This discriminates against enrollees who use cost-sharing assistance provided by drug manufacturers by offering more limited benefits – and higher cost sharing – to them as compared to other enrollees who have other forms of cost-sharing assistance, including family support. There is no clinical basis for this disparate treatment. Indeed, it treats enrollees worse simply because they have significant health needs that require certain drugs. Further, a 2019 study of impacts of copay accumulator on specialty drug adherence for patients with health savings accounts (HSA) versus patients with preferred provider organizations (PPO) found that HSA patients who fill autoimmune prescriptions had lower monthly fill rates and a higher risk of stopping their medications than PPO patients when accumulators were applied. This study suggests that the application of copay accumulator programs may affect patients' specialty drug adherence.[65]

Accumulator adjustment programs, especially applied in situations where there is no generic equivalent available, should be considered presumptively discriminatory, under either a disparate treatment or disparate impact theory of disability discrimination.[66] Once third-party patient assistance has been drawn down in accumulator adjustment programs, patients often face unexpected out-of-pocket costs. In a 2019 Kaiser Family Foundation (KFF) survey of prescription drug costs, among those currently taking prescription drugs, nearly one quarter of adults stated that it was difficult to afford their medications. Of patients who were unable to remain adherent to prescriptions due to cost, 20% skipped or delayed a dose. Skipping or delaying dosages may lead to negative health outcomes, especially for patients with chronic

[63] *Id.* Note that while the requirement to provide essential health benefits does not apply to the large group market, to the extent that large group health plans provide coverage of essential health benefits, the ACA's annual limitation on cost-sharing applies.
[64] PhRMA. Accumulator adjustment programs lead to surprise out-of-pocket costs and nonadherence, analysis finds. November 2020. https://catalyst.phrma.org/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds.
[65] Sherman BW, Epstein AJ, Meissner B, Mittal M. Impact of a co-pay accumulator adjustment program on specialty drug adherence. Am J Manag Care. 2019 Jul;25(7):335-340. PMID: 31318506.
[66] *See Schmitt*, 965 F.3d at 959; Doe v. CVS Pharmacy, Inc., 982 F.3d 1204, 1210 (9th Cir. 2020) (discussing Alexander v. Choate, 469 U.S. 287, 302 (1985)).

conditions.[67] HHS should state clearly that, when most or all patients with disabling chronic conditions face accumulator adjustment programs that increase their overall financial burden as compared to nondisabled patients, that is disability discrimination.

Similarly, copay maximizer programs can discriminate against individuals living with chronic conditions by imposing higher cost sharing on their medications unless a patient enrolls into a copay maximizer program. Copay maximizer programs skirt the protection of the ACA's annual limit on cost sharing and impose higher cost sharing on certain medications by designating them as non-Essential Health Benefits (non-EHB).[68] While there is no purported clinical reason to designate certain drugs as non-EHB and impose higher cost sharing, these copay maximizer programs shift higher costs of accessing these medications onto patients who decide not to enroll in the copay maximizer program or onto manufacturer cost-sharing assistance programs that are intended for and available to patients independently of the copay maximizer program. Copay maximizer programs also require patients to access their medication only at preferred specialty pharmacies, which can have a discriminatory impact on individuals living with chronic conditions, and in particular, patients with chronic conditions living in areas in which they may only have access to one or two independent pharmacies serving their area.[69] In a 2021 unpublished Avalere analysis on prescription drug cost sharing on specialty tiers in federally-facilitated exchanges and California's exchange, 93% of silver plans use coinsurance on specialty tier drugs. Given coinsurance can result in higher patient out of pocket costs than copayments, this disproportionately affects those with conditions who are prescribed specialty tier products and can make it harder for patients to afford these medications.[70]

Another potentially discriminatory practice is alternative funding programs, in which claims for branded specialty drugs are automatically denied by the PBM and patients are referred to an alternative funding vendor that facilitates enrollment into manufacturer free drug programs or other condition-specific charities or foundations designed to assist uninsured or underinsured patients.[71] Alternative funding programs allow commercially insured patients, who otherwise

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[67] Ashley Kirzinger, Lunna Lopes, Brian Wu, and Mollyann Brodie, KFF Health Tracking Poll -February 2019 Prescription Drugs (Kaiser Family Foundation, March 1, 2019), https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

[68] *See* David Cook, IPBC and SaveOnSP Training-20210216 1901-1, VIMEO (Feb 17, 2021), https://vimeo.com/513414094 (describing SaveOnSP's program to get the "most lucrative savings" by reclassifying specialty drugs as "non-essential," allowing SaveonSP to "operate outside of those [Affordable Care Act] rules"); PrudentRx Copay Program for Specialty Medications, https://personnel.ky.gov/KEHP/PrudentRx%20Overview.pdf (indicating that "certain specialty drugs do not qualify as 'essential health benefits'").

[69] *See* Express Scripts, SaveOnSP, https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp (last accessed on Aug. 21, 2022);

[70] Unpublished Avalere Analysis. "Percentage of Silver Plans Using Copay vs. Coinsurance and Average Cost Sharing by Formulary Tier, FFE States and CA, 2022". December 2021.

[71] *See* RxBenefits, Understanding Funding for Specialty Medications, https://www.rxbenefits.com/ebooks/understanding-alternative-funding-for-specialty/ (last accessed Aug. 21, 2022); Industry Experts Question Alternative Funding Companies That Carve Out Some Specialty Drugs, 'Abuse Charities,' AISHealth, Sept. 1, 2022, https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/ (last accessed Sept. 26, 2022).

may not be eligible for the manufacturer charities or foundations, to access funds intended for uninsured or underinsured patients. This in turn may cause patients with financial needs to compete for limited resources or funds and enhance the potential for discrimination for patients with disabilities and prescribed specialty products. These programs only exist for specialty drugs and thus disproportionately affect individuals living with chronic conditions who need these life-saving specialty medications. Individuals living with chronic conditions must undergo additional processes after their claim is denied – without any discernable clinical justification – which delays their therapy and potentially puts them at risk of poorer health outcomes.

We urge the Department to find accumulator adjustment programs, copay maximizers, alternative funding programs, and any other scheme for health plans or third parties to divert or profit from patient assistance as examples of presumptively discriminatory practices, as they disproportionately impact individuals and families living with chronic conditions, including those with disabilities. These programs also run counter to the intent of the ACA, which aims to increase affordability for health insurance coverage by requiring an annual limitation on out-of-pocket costs for EHB to apply throughout the private health insurance market.[72] In the individual and small group market, if a health plan includes covered drugs beyond the number of drugs covered by the EHB-benchmark plan, all of these covered drugs are considered EHB and "cost sharing paid for the drugs must count toward the annual limitation on cost sharing."[73] Extending this policy to all markets, whether insured or self-insured, and whether small or large, ensures that the ACA's consumer protection on out-of-pocket costs applies, as intended, to essentially all individuals with private health insurance.

Most Integrated Setting

The *Olmstead* decision prohibits unjustified segregation of individuals with disabilities.[74] PhRMA supports the integration provision in § 92.207(b)(6) that prohibits covered entities from having or implementing a benefit design that does not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to meet the needs of individuals with disabilities. As noted in the preamble, this might occur when a PBM (that is a covered entity) implements utilization management techniques that are more restrictive in the community than in an institutional setting.[75] For example, people in an institutional setting might be prescribed a medication that requires step therapy for someone with the same diagnosis in the community. This rule would appropriately prohibit this type of discrimination.

"Legitimate" reasons for denial of coverage (§ 92.207(c))

Section 92.207(c) permits a covered entity to deny coverage for items where it has a "legitimate, non-discriminatory" reason, such as when an insurer determines an item or service is not medically necessary, but this allowance is tempered by more specific language in the

[72] *See* Patient Protection and Affordable Care Act § 1302 (c)(1), 42 USC 18022 (c)(3); § 2707(b), 42 USC 300gg-6(b).
[73] 84 Fed. Reg. 227 at 289.
[74] *Olmstead v. L.C.*, 527 U.S. 581 (1999).
[75] 87 Fed. Reg. 47824 at 47873.

preamble that identifies instances where discrimination can emerge. PhRMA agrees HHS is right to be concerned that coverage denials could be a source of discrimination on the basis of disability and that utilization management (UM) practices could drive health disparities.

The preamble to the proposed rule describes the permissible use of UM, with the critical proviso that "excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate Section 1557."[76] For certain individuals with disabilities (such as those with HIV or certain cancers), dramatic advances in treatment over the last decade have begun to change these disabilities from life-threatening diseases into manageable chronic conditions. Physician-administered medicines, in particular, are a key component of treatments for many mental or physical impairments associated with disabilities, including certain cancers, multiple sclerosis, and some rare diseases—conditions for which there often are no therapeutic alternatives and/or for which the ability to tailor a treatment protocol to a patient's unique circumstances is evident (e.g., for patients needing a second line therapy). The proposed rule recognizes that medical necessity is based on an individualized determination, but should also be clear that medical necessity guidelines evolve based on generally accepted standards for care.[77]

Plan designs that exclude coverage of critical treatments for disabilities violate Section 1557's ban on discrimination on the basis of disability (and should therefore be cited as an example of benefit designs that violate Section 1557 in the final text of 45 C.F.R. § 92.207), and also violate the ACA's prohibition on Marketplace benefit designs that "have the effect of discouraging the enrollment in such plan[s] by individuals with significant health needs."[78] Therefore, HHS should specify that plans must offer a comprehensive medical benefit that includes robust coverage of a wide range of drug therapies. Otherwise, health plans could attempt to restrict prescription drug coverage by excluding the innovative medications that many patients with disabilities need.

A recent study published in *Health Affairs* found that more than half of step therapy policies developed by commercial health plans were more restrictive than recommended clinical guidelines, meaning patients and providers may have to overcome time-consuming hurdles imposed by health plans before a medicine is covered.[79] The researchers concluded that "[t]hese findings raise questions about potentially overly restrictive step therapy protocols, as well as concerns that variability across health plans makes protocols onerous for patients and practitioners alike." Additionally, the consistency of step therapy protocols varied within and across plans. This raises important questions about the potential for health plan discrimination against certain populations, including patients who may have fewer resources to navigate unjustifiably burdensome protocols.

[76] 87 Fed. Reg. 47824 at 47874.
[77] *See* 87 Fed. Reg. 47824 at 47873.
[78] Patient Protection and Affordable Care Act § 1311(c)(1)(A).
[79] Lenahan, K. et al. Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans. November 2021. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.00822.

As the Department enforces Section 1557, PhRMA recommends that HHS analyze the potential effects of UM (e.g., prior authorizations, step therapy) on health disparities. Section 1927 of the Social Security Act requires state Medicaid programs to cover medically- accepted indications of all FDA-approved outpatient drugs included in a manufacturer's rebate agreement with the Secretary of HHS (with limited exceptions). When FDA approves a new therapy that could substantially improve the chance of survival or quality of life for patients, there remain various access barriers for patients covered by certain state Medicaid programs.

PhRMA therefore urges HHS to monitor utilization of innovative new therapies to identify disparities across states or delivery systems. HHS should focus on treatments that have been designated by the FDA as "Breakthrough Therapies" because they are (1) intended to treat a serious condition, and (2) the clinical evidence "indicates that the drug may demonstrate substantial improvement over available therapy" as well as therapies approved through the accelerated approval pathway. We recommend that HHS identify additional therapies—pharmacological and otherwise—to track by working with patient advocacy organizations, provider groups, and other stakeholders.

In the commercial market, utilization management has increased for drugs across a wide array of therapeutic areas, including autoimmune disorders, asthma/allergies, cardiovascular disease, diabetes, and HIV. All of these have higher rates of impact among communities of color and underserved populations.[80,81,82] Exchange plans are also more likely to impose UM requirements than employer plans, which could disproportionately impact QHP enrollees.[83] Given the proliferation of UM, especially in Marketplace plans, systematic analysis of whether health plan-imposed administrative burdens and coverage restrictions discriminate against underserved communities is necessary.

HHS should also analyze the potentially discriminatory effects of UM within Medicaid, particularly as it relates to access to innovative, life-saving, and curative therapies. For example, in 2014, a new therapy to cure hepatitis C was approved by the FDA. This treatment was subject to UM and coverage delays, making it more difficult for Medicaid beneficiaries to access. A 2017 Medicaid and CHIP Payment and Access Commission (MACPAC) report found that "[a]bsent concerted federal action, State Medicaid programs implemented a range of policies to try to manage…new HCV treatments" and that at least 27 States required prior authorization for the drug in the months immediately following its release while many others limited access to those with the most severe disease.[84] This same report also referenced a Brigham and Women's

[80] Impact on Racial and Ethnic Minorities, HIV.gov, https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racialand-ethnic-minorities.
[81] Minority Health & Health Disparities, NIH: National Institute of Allergy and Infectious Diseases, https://www.niaid.nih.gov/research/minority-health-disparities.
[82] HHS Office of Minority Health, Policy and Data, https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlID=4.
[83] Avalere Health. "Utilization Management Trends in the Commercial Market, 2014-2020." November 24, 2021. https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf.
[84] Bruen, Brian, et al. "High-cost HCV Drugs in Medicaid: Final Report." Report for Medicaid and CHIP Payment and Access Commission, Contract # MACP16406T2, January 2017. https://www.macpac.gov/wp-content/uploads/2017/03/High-Cost-HCV-Drugs-in-Medicaid-Final-Report.pdf.

Hospital study that observed great variation in the use of the newly approved medication, "ranging from 2% of all prescriptions for HCV drugs in Texas to 44% in Hawaii."[85] Finally, the MACPAC report noted a few States also placed stricter clinical limits on access beyond what was approved on the FDA label.[86] With more therapies in the pipeline for development, PhRMA urges HHS to include provisions in the final 1557 rule to ensure all individuals covered by public programs are not subject to potentially discriminatory UM and coverage delays in accessing needed medications and therapies.

Network Adequacy

The proposed rule requests comment on how Section 1557 might apply to health plans' provider networks, their development, and any limitations or denials of care that can result. As the Department considers the situations in which plan choices and design could be discriminatory, we urge HHS to insert in the preamble to the final rule an example of discriminatory contracting with pharmacies, in addition to the other provider and facility types identified in the proposed rule.

Network adequacy standards can impact access for certain prescription drugs, especially among people with chronic conditions, when a prescription drug is covered by a plan, but it needs to be dispensed or administered by specialized providers who are out-of-network, or by a specialty pharmacy. Specialized providers and specialty pharmacies are often utilized when therapies for complex, chronic conditions require special management, including additional monitoring and support services that retail pharmacies may not be able to offer. If a patient receives an otherwise covered drug from an out-of-network provider or pharmacy, which might be the only way to receive the drug locally, the plan could consider the medicine out-of-network and might not count cost sharing toward the maximum out-of-pocket limit, creating an affordability barrier. Overly narrow pharmacy networks can have the practical impact of dissuading patients with certain complex, chronic conditions from enrolling in a plan in the first place, and thus, the adequacy of pharmacy networks should also be included in HHS's consideration.

Network adequacy standards have also been found to impact provider reimbursement rates. Differences in provider reimbursement may drive disparities in access to care, as low provider reimbursement rates are likely to lead to lower provider access among Medicaid beneficiaries.[87] Researchers have suggested that reducing the payment gap in reimbursement among all providers between Medicaid and private insurers would reduce two-thirds of care access disparities for adults and eliminate these disparities for children entirely.[88] For example,

[85] *Ibid*.
[86] *Ibid*.
[87] The Commonwealth Fund. Ford, Tiffany and Michener, Jamila. "Medicaid Reimbursement Rates Are a Racial Justice Issue." https://www.commonwealthfund.org/blog/2022/medicaid-reimbursement-rates-are-racial-justice-issue
[88] Allen, Eva H., Clemans-Cope, Lisa, Coquillat, Sarah, Eggleston, Alexa, Taylor, Kima Joy, and Ramos, Christal. "Improving Substance Use Services for Youth: Policy Opportunities for State Medicaid/CHIP Programs." The Urban Institute, January 2022. https://www.urban.org/sites/default/files/publication/105388/improving-substance-use-services-for-youth_1.pdf

one study found that increasing Medicaid primary care rates by $45 per service could reduce inequities in access by 70 percent.[89] Researchers have also concluded that increasing provider reimbursement rates is associated with an increase in retention in care for Medicaid beneficiaries with HIV.[90] Finally, stakeholders have noted the Medicaid statutory requirement that mandates States ensure equal beneficiary access may not be uniformly enforced, which is likely to create conditions leading to an inequitable provider reimbursement structure.[91] PhRMA urges HHS to consider the impact of provider reimbursement on network adequacy, specifically the discriminatory nature of low provider rates, and include language clearly outlining this as discriminatory conduct in the final Section 1557 rule.

To determine whether a certain network design is discriminatory, PhRMA urges the Department to consider access measures such as medication adherence, prescription fill times, uptake of innovative therapies that are at risk of access barriers, and complaints and appeals regarding delayed/denied access to specialists and drugs. To support the identification of population-specific access challenges and advance health equity, such data should be stratified by age cohort (children, non-elderly adults, elderly adults), as well as by race/ethnicity, gender, and LGBTQ+ identification.

Value Assessment

PhRMA applauds HHS for recognizing growing concerns that certain value assessments, including on metrics such as the quality-adjusted life-year (QALY), can be used in a way that discriminates against individuals due to their race, LGBTQ+ identification, national origin, sex, age, disability, or health status. While rigorous and patient-centered assessments are a valuable tool to inform decision-making, we are concerned that inappropriate use of health technology assessments (HTA) may result in significant access barriers for some patients.

As outlined in PhRMA's principles for value assessment,[92] we support the use of sound evidence for informed decision-making in health care, including the use of assessments by commercial health plans. When designed well and used appropriately, emerging frameworks to assess the value of medical tests, treatments and health care services represent one of the many tools that can be useful to support well-informed, patient-centered health care. As our principles note, it is imperative that value assessments:

[89] Alexander, Diane., Schnell, Molly. "The Impacts of Physician Payments on Patient Access, Use, and Health," Working Paper. doi: https//doi.org/10.3386/w26095
[90] Pan Z., Dahman B., Bono RS, Sabik LM, Belgrave FZ, Nixon DE, Kimmel AD. "Physician reimbursement and retention in HIV care: Racial disparities in the US South," Preprint. medRxiv 2021.08.16.21262053; doi: https://doi.org/10.1101/2021.08.16.21262053
[91] The Commonwealth Fund. Ford, Tiffany and Michener, Jamila. "Medicaid Reimbursement Rates Are a Racial Justice Issue." https://www.commonwealthfund.org/blog/2022/medicaid-reimbursement-rates-are-racial-justice-issue
[92] PhRMA. Principles for Value Assessment Frameworks. 30 March 2016. Available at: https://www.phrma.org/resource-center/Topics/Cost-and-Value/Principles-for-Value-Assessment-Frameworks

- **Describe a sound process** that is clear, reproducible and transparent, with opportunity for input and a strong role for patients and physicians.
- **Support patient-centered care** by considering patient preferences and heterogeneity, appropriately communicating results, and avoiding misuse.
- **Deliver reliable, relevant information** by using rigorous, transparent methods that rely on the full range of evidence and prioritize longer-term and broader outcomes.
- **Value continued scientific and medical progress** by accounting for personalized medicine, the step-wise nature of progress, and the inherent value of innovation.
- **Take a system-wide perspective** on value by examining the full range of tests, treatments, care management approaches and health care services.

Additionally, we strongly believe that value assessments should be used to enable equitable care by improving rather than restricting individual patients' access to the care that is most appropriate and valuable to them. There are a number of ways in which traditional methods of value assessment discriminate against underrepresented and underserved populations. Some of these issues are common in, but not unique to, methods that rely on cost-per-QALY judgments of value. For example, when used inappropriately, value assessments can underestimate the benefits of certain treatments and procedures by ignoring the pre-existing health deficits that may exist due to numerous inequities such as the negative consequences of social determinants of health[93] and discrimination,[94] including reduced access to care,[95] reduced quality of care,[96] and higher prevalence of disease and disease-related mortality.[97] For example, a medicine that extends the life of patients with diabetes and visual impairment is valued as providing 15% fewer "years of optimal health" (fewer QALYs) to a Black patient compared to a White patient with the same diseases.[98] Other quality-of-life factors may also be valued by individuals or groups of individuals differently and, by ignoring population diversity and health disparities, HTAs can generate biased results that can exacerbate system inequities, and create access barriers for underserved populations and those at higher risk for poor health outcomes.[99] As an example, treatments that require less frequent visits to a provider or delivered by mail could be viewed as

[93] National Snapshots of Social Determinants of Health. HealthyPeople.gov. Available at: https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health/national-snapshot
[94] Boyd RW, Lindo EG, Weeks LD, McLemore M. On Racism: A New Standard for Publishing on Racial Health Inequities. Health Affairs. 2 July 2020. Available at: https://www.healthaffairs.org/do/10.1377/hblog20200630.939347/full/
[95] Artiga S and Orgera K. Key Facts on Health and Health Care by Race and Ethnicity. Kaiser Family Foundation. 12 Nov 2019. Available at: https://www.kff.org/report-section/key-facts-on-health-and-health-care-by-race-and-ethnicity-introduction/
[96] 2019 National Healthcare Quality and Disparities Report. Content last reviewed June 2021. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/research/findings/nhqrdr/nhqdr19/index.html
[97] Minority Population Profiles. Office of Minority Health. Available at: https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=26
[98] McCollister KE, Zheng D, Fernandez CA, Lee DJ, Lam BL, Arheart KL, Galor A, Ocasio M, Muenning P. (2012). "Racial Disparities in Quality-Adjusted Life-Years Associated With Diabetes and Visual Impairment." Diabetes Care. 35:1692–4. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3402250/pdf/1692.pdf
[99] Jones J, Schmitt J, Wilson V. 50 Years After the Kerner Commission. Economic Policy Institute. 26 February 2018. https://www.epi.org/publication/50-years-after-the-kerner-commission/

of higher value to Hispanic and Black patients who are more likely to live in a neighborhood impacted by pharmacy deserts.[100]

The QALY, in particular, has been critiqued as having insufficient sensitivity to measure small but clinically meaningful changes in health status such as those we see in cancer patients.[101] For example, any methodology valuing quality of life of patients on the mental health spectrum can be incredibly subjective[102] and extremely young or old patients are valued differently with a QALY for a patient with multiple sclerosis is worth half as much as a healthy, young individual and a patient over the age of 80 is worth approximately 30% less simply because of their age.[103]

Although patient groups have repeatedly criticized value assessments methods and processes for not incorporating the effects of racism, prejudice, stigma, or social inequalities in their assessments, HTAs are still often generated without adequately representing diverse stakeholders, their input, or their experiences. According to Tufts Medical Center, fewer than 5% of cost-effectiveness analyses stratify results by race or ethnicity.[104]

It is also critical that value frameworks are not misused in ways that impose centralized, one-size-fits-all policies, impede patients' and physicians' ability to tailor care to individual needs and preferences, and hinder progress against unmet medical need. Concerns about misuse of value assessment is what led to the existing prohibition against utilization of the QALY and similar measures as a threshold to determine coverage, reimbursement, or incentive programs in the Medicare program.[105] This protection remains critical.

The dangers of misusing value frameworks are seen in patient access issues faced outside the U.S. In foreign countries where governments use value assessments as part of a price setting process, patients in those countries face significant barriers to access. Patients in the United Kingdom, Canada, and Australia only have access to 59%, 44%, and 34% of the medicines launched globally, respectively.[106]

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[100] Guadamuz J, Wilder JR, Mouslim MC, et al. Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared with White or Diverse Neighborhoods, 2007 – 15. Health Affairs. May 2021. https://doi.org/10.1377/hlthaff.2020.01699

[101] Garau M, Shah KK, Mason AR, Wang Q, Towse A, Drummond M. Using QALYs in Cancer. Pharmacoeconomics 29, 673–685 (2011). https://doi.org/10.2165/11588250-000000000-00000

[102] Knapp M, Mangalore R. "The trouble with QALYs...". Epidemiol Psichiatr Soc. 2007 Oct-Dec;16(4):289-93. doi: 10.1017/s1121189x00002451. PMID: 18333423.

[103] Value Our Health. (2021). "What is Your Life Worth Around the World?" Available at: https://valueourhealth.org/voh-world-map/

[104] Lavelle TA, Kent DM, Lundquist CM, Thorat T, Cohen JT, Wong JB, Olchanski N, Neumann PJ. (2018). Patient Variability Seldom Assessed in Cost-effectiveness Studies. Med Decis Making. 38(4):487-494. doi: 10.1177/0272989X17746989. Epub 2018 Jan 19. PMID: 29351053; PMCID: PMC6882686.

[105] The Patient Protection and Affordable Care Act. PL 111-148. 3-23-2010.

[106] PhRMA analysis of IQVIA MIDAS and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA), Australia Therapeutic Goods Administration (TGA) and Health Canada data. July 2022. Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

No single value assessment – those that employ metrics like the QALY or otherwise – should be used alone to set rigid rules that impede or delay patient access to care. As well-structured assessments can be a valuable tool, HHS should ensure that plans that rely on value assessment methods are transparent and impose clear oversight to ensure value assessments are not misused in a way that can hinder patient access to effective treatments.

Use of Clinical Algorithms in Decision Making (§ 92.210)

Consistent with our priority of building a more just, equitable health care system, PhRMA believes that diversity, equity, and inclusion are essential to the discovery of new medicines and that people of all ethnic and racial backgrounds should have equitable access to treatment and health care services.[107] Like HHS, PhRMA is concerned about the potential discriminatory harms, such as inequities to access treatments and other health care necessities, that can be caused by clinical algorithms if they are not designed, implemented, used, or monitored in an appropriate and ethical manner.[108] PhRMA agrees that the "overreliance on algorithms in clinical decision-making can be discriminatory" and is largely in support of the proposed provision.

As described by the Agency for Healthcare Research and Quality, clinical algorithms are defined as "mathematical formulas and models that combine different variables or factors to inform a calculation or an estimate—frequently an estimate of risk."[109] Clinical algorithms are broadly utilized in healthcare decision-making tools, such as clinical guidelines, clinical support tools, and treatment decision guides. However, researchers have criticized the use of race in the algorithms due to the entrenched association between race and racism, which leads to decisions being directed away from communities of color.[110] For example, the American Heart Association's 2022 heart failure guidelines include a recommendation to utilize the American Heart Association's Get with the Guidelines (GWTG) Heart Failure Risk Score, which aims to predict the likelihood of inpatient mortality among patients hospitalized for heart failure. In practice, physicians can use the risk score to direct medical treatment among heart failure among patients with higher probability of mortality. However, the risk score adds three points for patients who are 'nonblack'; thus, automatically assigning a lower risk score to Black patients. This may result in Black patients being less likely to be treated for heart failure. The developers of the GWTG Heart Failure Risk Score recently have acknowledged the pitfalls associated with included race in the clinical algorithm and have made the incorporation of race in the score optional.[111]

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[107] PhRMA, "Building a Better Health Care System: PhRMA's Patient-Centered Agenda" https://phrma.org/report/Building-a-Better-Health-Care-System-PhRMAs-Patient-Centered-Agenda
[108] Christensen DM, Manley J, Resendez J. Medical Algorithms Are Failing Communities of Color. Health Affairs. September 9, 2021. DOI: 10.1377/forefront.20210903.976632.
[109] Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare. Agency for Healthcare Research and Quality. January 2022. https://effectivehealthcare.ahrq.gov/products/racial-disparities-health-healthcare/protocol
[110] Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms. NEJM. 2020; 383: 874 – 882. DOI: 10.1056/NEJMms2004740.
[111] MDCalc Statement on Race. MDCalc. Available at: https://www.mdcalc.com/race. Accessed 15 August 2022.

If designed, implemented, used, or monitored inappropriately, clinical algorithms can cause significant and potentially unrecognized harm to patients, perpetuate biases, stereotypes, and discriminatory practices, and may entrench and deepen existing health inequities, particularly among communities of color.[112] PhRMA agrees that the Section 1557 rulemaking provides an important opportunity for HHS, providers, and plans to identify current challenges and provide feedback on how the appropriate usage of clinical algorithms and other forms of automated or augmented decision-making should be governed in the future.

PhRMA supports the adoption of the proposed rule recognizing that a covered entity's inappropriate use of clinical algorithms in its decision-making may result in prohibited discrimination and specifically, the approach of encouraging covered entities to assess the impact of clinical algorithms on potential discriminatory design and impact, especially with respect to patients in medically underserved communities. PhRMA agrees that the scope of this rule should be broadened beyond clinical algorithms to include any automated decision-making tools or models, including machine learning and artificial intelligence.[113] We encourage HHS to consider the potential impact of its proposed regulations on covered entities and the future development of new clinical algorithms and tools.

PhRMA supports the proposal to make explicit that covered entities are prohibited from discriminating negatively against populations through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557.[114] We encourage the HHS to provide guidance to covered entities prior to the implementation and effective date of the clinical algorithm regulation on best practices for reducing inequities associated with clinical decision algorithms, and propose that these best practices be based on principles of equity, justice, and patient-centeredness, as supported by PhRMA's Better Way Agenda and PhRMA's Equity Initiative.[115]

We suggest that HHS require covered entities (e.g., health insurance companies, medical institutions, and associated providers) to work with experts in community-based research/advocacy to ensure that the concerns and needs of underserved communities are recognized and addressed in the data collection and use processes that feed into the development of clinical algorithms that they use. PhRMA suggests that federal regulators consider testing, piloting, and facilitating the development of best practices for the design, implementation, use, and monitoring of clinical algorithms to ensure they appropriately account for social determinants of health, stigma, and socially lived experiences across a broad range of cultures and backgrounds. We also encourage HHS to engage with community-based organizations and community-based leaders to foster trust-worthy relationships and improve communication and outreach efforts within diverse communities. HHS should consider offering incentives to

[112] Christensen DM, Manley J, Resendez J. Medical Algorithms are Failing Communities of Color. Health Affairs. Sept 2021. https://www.healthaffairs.org/do/10.1377/forefront.20210903.976632/full/
[113] Estiri H et al., An objective framework for evaluating unrecognized bias in medical AI models predicting COVID-19 outcomes. J Am Med Inform Assoc. 2022 Aug; 29(8): 1334–1341. doi: 10.1093/jamia/ocac070
[114] 87 Fed. Reg. 47824.
[115] PhRMA, "Building a Better Health Care System: PhRMA's Patient-Centered Agenda." https://phrma.org/report/Building-a-Better-Health-Care-System-PhRMAs-Patient-Centered-Agenda

community-based organizations currently serving as partners to increase recruitment and engagement of underserved communities.

HHS should work with covered entities and others to identify algorithms that have demonstrated a positive impact on health equity and have the potential to reduce detrimental discrimination in the clinical setting. In addition, HHS should clarify that the forthcoming potential regulation does not prohibit or penalize the use of clinical algorithms conducted in the context of research in accordance with current applicable research standards.

Subpart D – Procedures

In § 92.301 of the proposed rule, HHS relies principally on the enforcement mechanisms of the underlying statutes to enforce Section 1557.[116] In addition, § 92.303 lays out the procedures the Director of the HHS Office for Civil Rights (OCR) must follow to request information regarding a claim of discrimination, seek voluntary resolution of the claim and, if noncompliance is found, initiate enforcement that could include fund suspension or termination. Given the number of disabilities for which prescription drugs are a primary treatment, and the fact that prescription drug costs are easier to predict than other forms of health care spending—which makes restrictive drug coverage a highly effective tool for discouraging enrollment by high-cost individuals—it is particularly important that HHS develop specific mechanisms to monitor formulary practices to ensure that formularies are not used to discriminate against patients with specific disabilities. For reasons discussed above, monitoring coverage of physician-administered "medical benefit" drugs is also critical to prevent benefit designs that discriminate against patients with specific disabilities.

We also support the proposed rule's related provision in § 92.6 (in Subpart A) authorizing the Director of OCR to order remedial action to overcome the effects of discrimination. This could include, where necessary, taking remedial action with respect to people who are no longer participants in the health program or activity or who would have been participants but for the discrimination. Further the proposed rule would encourage entities' voluntary course corrections when they recognize the need to bring their health programs or activities into compliance with the nondiscrimination protections.

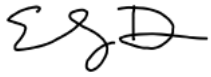
While HHS and the Director of OCR must actively enforce Section 1557, private parties will also play an important role in monitoring and enforcement, particularly given that the beneficiaries of federally funded health programs or activities are often the first to observe the effects of discrimination. To help HHS and individuals monitor adherence to Section 1557's requirements, the Department should require health plans to publish and make easily available to individuals up-to-date formularies, reflecting the cost sharing and UM rules applicable to each drug. Individuals should be able to easily search plan formularies by brand or generic drug name to compare a complete set of cost-sharing or tiering information, as well as information on available pharmacy networks and how medicines count towards plan-level deductibles. If this

[116] The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part.

information is not clear and easily available, consumers may be confused by the cost-sharing information provided for each tier of medicines and may not realize they also have to reach a plan's deductible.

PhRMA appreciates the opportunity to provide comments regarding this proposed rule. Please feel free to contact Emily Donaldson at 202-835-3420 or edonaldson@phrma.org if we can provide any further information or if you have any questions about the topics discussed in our comments. We look forward to continuing to engage with the HHS on these important issues.

Sincerely,



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