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October 3, 2022

Melanie Fontes-Rainer
Director
Office of Civil Rights
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

RE: Nondiscrimination in Health Programs and Activities Proposed Rule – AHIP Comments

Dear Director Fontes-Rainer:

Every American deserves access to high-quality, affordable health care, regardless of race, color, national origin, sex, gender identity, sexual orientation, age, or disability.¹ AHIP firmly believes in this commitment, and we strongly support the overarching goal to promote equal access to health care. We also support federal law protections that prohibit discrimination and ensure that care is available and accessible to every American.

We appreciate the opportunity to provide comments in response to the Department of Health and Human Services' (HHS) Proposed Rule on Nondiscrimination in Health Programs and Activities published in the *Federal Register* on August 4, 2022.

AHIP and our health insurance provider members applaud HHS' efforts to promote health equity and reduce health care disparities. For example, health insurance providers have a demonstrated track record of creating innovative approaches to improve health by targeting social determinants of health, implementing innovative care management and intervention programs, and engaging stakeholders across the health care industry to align on shared priorities. As part of our commitment to reducing disparities and increasing access to care, health insurance providers develop and implement effective resources to individuals with limited English proficiency (LEP) and individuals with disabilities to ensure they have meaningful access to language services and important supports to effectively use their health insurance.

In our comments, we demonstrate our member health insurance provider's commitment to provide health coverage that does not discriminate while ensuring the provisions of the proposed

¹ AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and to help create a space where coverage is more affordable and accessible for everyone.

rule are workable, balance the cost and burden of administrative processes, and ensure people can understand and access their high-quality care.

Our recommendations address:

- **Nondiscrimination:** Discrimination and inequality are wrong in any form. AHIP strongly supports federal law protections that prohibit discrimination based on race, color, national origin, sex, gender identity, sexual orientation, age, or disability. We support both the proposed HHS provisions and the corresponding amendments to program-specific regulations. We support these provisions taking effect 60 days after publication of the final rule.
- **Support for Enrollees with Limited English Proficiency and Individuals with Disabilities:** Health insurance providers are committed to ensuring that Americans with limited English proficiency and individuals with disabilities can successfully navigate the health care system, understand the information provided by their health plan, and access the services they need. We offer detailed comments on how HHS should maintain regulatory flexibility to focus on quick and streamlined access to interpretation, with written translations provided upon request. We encourage HHS to work with stakeholders to develop alternative approaches that effectively connect people with access to language services they need, such as including a universal access symbol on member communications that connects enrollees directly with relevant resources.
- **Notice Requirements:** AHIP appreciates the Department's efforts to streamline requirements and reduce the administrative burden of providing notices to consumers. AHIP supports HHS' optional approaches for opt-out and language preference tracking. Our comments include additional recommendations to modify notice timing and frequency, as well as other suggestions to further improve the notice requirements.
- **Clinical Algorithms:** AHIP recommends HHS convene a stakeholder process to gather additional input about the use and application of clinical algorithms. This process also should ensure that any related provisions provide clear definitions and a regulatory compliance framework.
- **Effective Date:** To allow for enough time to implement the proposed rule's provisions, AHIP recommends that HHS extend the effective date for requirements related to notices, policies, procedures, and training to 12 months following the publication of a final rule in the *Federal Register* and provide an 18-month good faith safe harbor for commercial

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market compliance with the 2016 final rule and Medicare market compliance with the Multi-language Insert (MLI).

We provide detailed comments on these and other provisions of the rule in the attached recommendations. We look forward to the opportunity to work with the Department on policies that promote our shared goal of equitable access to high-quality, affordable health care coverage for every American.

Sincerely,

A handwritten signature in cursive script that reads "Jeanette Thornton". The signature is written in black ink and is positioned above the printed name.

Jeanette Thornton
Executive Vice President of Policy and Strategy
AHIP

Attachment

AHIP Comments on Nondiscrimination in Health Programs and Activities Proposed Rule

AHIP's detailed comments on the proposed rule are organized by the following topics:

- I. Nondiscrimination
- II. General Provisions
- III. Compliance Obligations
- IV. Notice Requirements, Meaningful Access, and Effective Communication
- V. Other Provisions
- VI. Requests for Comment

I. Nondiscrimination

Discrimination Prohibited (§ 92.101)

HHS proposes a general prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability under any covered health program or activity and clarifies that discrimination on the basis of sex includes discrimination on the basis of sex stereotypes, sex characteristics, intersex traits, pregnancy or related conditions, sexual orientation, and gender identity.

Discrimination and inequality are wrong in any form. Every American deserves access to high-quality, affordable health care, regardless of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. AHIP applauds the Administration's efforts to ensure that everyone has access to health care without discrimination and will continue to work with other health care leaders to eliminate barriers to care and promote better health.

Recommendation:

- **We strongly support federal law protections that prohibit discrimination based on race, color, national origin, sex, gender identity, sexual orientation, age, or disability.**

Nondiscrimination in Health Insurance and Other Health-Related Coverage (§ 92.207)

HHS proposes to prohibit covered entities that provide or administer health insurance coverage or health-related coverage that receive federal financial assistance from discriminating on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage. This includes cancelling, limiting, or refusing to issue or renew coverage, denying or limiting claims, imposing additional coverage limitations based on protected classes, or implementing discriminatory marketing practices or benefit designs.

AHIP applauds HHS’ stated goal of advancing health equity and reducing disparities based on race, national origin, disability, gender, sexual orientation, and other protected classes. AHIP and its member health insurance providers strongly agree with HHS that it is critical to progress beyond a consideration of broad demographic categories in our health equity programs and to identify and address disparities within and among subgroups. Through health equity data collection and analysis and evidence-based studies, our member health insurance providers are identifying health disparities within specific subgroups and in specific geographic areas and developing focused strategies to close care gaps and address unique needs.

Health insurance providers implement specific programs, like chronic care management or social determinants of health (SDOH) interventions, to improve health of their enrollees. In some cases, this includes identifying enrollees in need of specific clinical interventions, provider access, transportation or housing assistance, work placement, training opportunities, community-based resources, and more. Separately, we are awaiting future rulemaking under the *Health Insurance Portability and Accountability Act* (HIPAA) to address care management and similar programs and the permitted uses and disclosures of protected health information in these situations to benefit individuals. If health plans are required to provide services that address chronic care, SDOH, or other similar programs “equally” to all enrollees rather than “equitably” target services to those in need based on health or socioeconomic condition, plans will be limited in their ability to provide appropriate services and scale and sustain these programs. Instead, HHS could consider an approach similar to the Wellness rules for group health plans that generally allow for more favorable treatment for individuals with medical needs.²

AHIP and its member health insurance providers are concerned that the new proposed rules under Section 1557 may unintentionally limit our member health insurance providers’ ability to develop effective programs and initiatives to reduce health disparities. Specifically, where our member health insurance providers have identified a disparity within a population

² 71 Fed. Reg. 75014

subgroup and/or in a specific geographic region, they need the flexibility to pursue focused programs to address the issue. Such programs may include, but are not limited to, individual outreach to enrollees of a subgroup through the care management process, tailored marketing to a subgroup to address a particular health concern, or targeted quality programs and investment of resources to ensure accessibility of certain services in a particular geographic area or for a population subgroup. We request that HHS clarify in the final rule that such actions taken to reduce health disparities would not violate Section 1557's nondiscrimination requirements.

Recommendation:

- **Clarify that targeted chronic care management, social determinants of health interventions, and other programs are permissible under the proposed rule.**

II. General Provisions

Purpose and Effective Date (§ 92.1)

HHS proposes the effective date of the regulation to be 60 days after the publication of a final rule in the Federal Register, with an exception for provisions that require changes to health insurance or group health plan benefit design. In these cases, the effective date will be delayed to the first day of the plan year beginning on or after the year immediately following the rule's effective date.

We recommend the following implementation timeline following publication of a final rule in the *Federal Register*:

- *60 Days*: Effective date for nondiscrimination requirements related to sexual orientation and gender identity.
- *Start of the plan year beginning on or after the year immediately following the rule's effective date*: Effective date for proposals that require benefit changes, with flexibility for plans to accommodate benefit changes and materials development if a rule is finalized close to open enrollment, plan renewal or related deadlines.
- *12 Months*: Effective date for provisions related to notices, policies, procedures, and training programs.
- *18 Months*: End of good faith safe harbor for commercial market compliance with the 2016 final rule and Medicare market compliance with the Multi-language Insert (MLI).

Additional detail on the rationale for our recommended timeline follows below.

Adequate Time to Implement

AHIP strongly supports reinstating nondiscrimination requirements related to sexual

orientation and gender identity within 60 days of publication of a final rule. However, 60 days is not enough time for health insurance providers to come into compliance with the rule's other administrative requirements. For example, the process for updating notices includes developing and reviewing new content, working with vendors and other third parties, sourcing materials and navigating supply chain challenges and shortages, updating systems and preparing additional mailings, obtaining regulatory approval in certain cases, and other activities that take significant effort to complete. Some health insurance providers have continued to comply with the 2016 rule's provisions, while others have made modifications based on the 2020 rule's updated requirements, but under either circumstance, it will be necessary to review current procedures, hire or train staff, and make any required updates to achieve compliance with this rule's provisions.

Additionally, the effective date of the plan year beginning on or after the year immediately following the rule's effective date for proposals that require benefit changes could be challenging depending on when the rule is finalized. In the Exchange market, qualified health plans (QHPs) are finalized in the fall, Medicare Advantage and Part D plan bids are submitted in June, and employer plans have renewal dates throughout the year. Given that some plan documents are reviewed by state Departments of Insurance, additional time is necessary to refile and update previously approved documents. HHS should extend the compliance date for provisions related to notices, policies, procedures, and training programs to 12 months following the publication of a final rule to allow additional time for covered entities to come into compliance with the rule and provide flexibility to accommodate various plan renewal materials development deadlines and making additional changes to comply with the final rule's requirements.

Good Faith Safe Harbor Compliance for 2016 Rule and Multi-language Insert

Today, many health insurance providers provide notices in compliance with the 2016 rule in the commercial market or the MLI under Medicare Advantage to support language services for their limited English proficiency (LEP) individuals to ensure they have knowledge and access to the services and supports needed to interact with their health insurance provider. Recognizing these processes are not completely compliant with the new proposed requirements, AHIP recommends that HHS adopt an 18-month safe harbor that addresses the following scenarios: 1) Adherence to the Section 1557 2016 rules for language access for the commercial market; and 2) Use of the MLI for the Medicare market. Both safe harbors will promote continued access for LEP individuals and individuals with disabilities while allowing plans additional time to review the new requirements, analyze current processes and procedures, and come into compliance with the rule.

Compliance with the rule will require modifications to existing materials, systems, and processes especially given the significant changes between the 2016 and 2020 requirements. Additionally, required changes related to the No Surprises Act, Transparency in Coverage

final rule, network adequacy and other concurrent regulatory implementations, the ongoing COVID-19 public health emergency and its eventual wind-down, and supply chain and labor market shortages pose significant challenges and increase demand for limited resources.

Changing requirements and compliance expectations every few years on something as significant as the Section 1557 requirements create uncertainty for health insurance providers, requires systems rework and process adjustments, and ultimately raises consumer costs. Such changes also raise potential Administrative Procedure Act (APA) issues, as regulations engender reliance interests, and changes should consider—and seek to avoid unnecessarily disrupting such reliance interests. HHS should work with stakeholders to finalize the proposals in this rule and establish a consistent framework across all impacted programs, avoiding minor variations in programmatic requirements that add additional costs.

Recommendations:

- **Support the proposed 60-day effective date for reinstating nondiscrimination requirements related to sexual orientation and gender identity.**
- **Provide an 18-month safe harbor for language access compliance with the 2016 rule for the commercial market and the MLI for Medicare Advantage.**
- **Extend effective date for requirements related to notices, policies, procedures, and training to 12 months following the publication of a final rule in the Federal Register and provide flexibility for plans depending on when a rule is finalized.**
- **Promote regulatory stability and consistent requirements for covered entities.**

Application and Definitions (§§ 92.2 and 92.4)

HHS proposes to reinstate the previous 2016 interpretation of “covered entity” to include: 1) every health program or activity, any part of which receives federal financial assistance, directly or indirectly, from the Department; 2) every health program or activity administered by the Department; and 3) every program or activity administered by a Title I entity, including Federally-facilitated Exchanges and State Exchanges. HHS proposes a definition of “federal financial assistance” to include grants, loans, and other types of assistance such as credits, subsidies, and contracts of insurance, including but not limited to Medicaid and CHIP, Medicare Parts A, B, C, and D, and HHS grant programs. HHS also proposes a definition of health program or activity to include operations of any entity principally engaged in the provision or administration of health insurance coverage or other health-related coverage, and all covered entity operations would be subject to the rule’s requirements.

Excepted Benefits

Excepted benefits are specific products with separate benefits from traditional health insurance coverage. There are four statutorily defined categories of excepted benefits, each of which is “excepted” from the *Affordable Care Act* (ACA) and other health coverage mandates as long as it meets certain requirements. These categories define distinct types of benefits and products. For example, some of these products, such as dental and vision plans, and Medicare supplemental insurance (Medigap), can cover additional benefits not included in major medical plans. Other excepted benefits, such as fixed indemnity excepted benefits and specified disease coverage, are specifically designed not to coordinate with other coverage and pay benefits regardless of whether the medical event triggering benefits is covered under another plan, providing an additional layer of valuable financial protection. The cash benefit under such policies may be used to cover out-of-pocket expenses, or other expenses, such as travel or lost income, that can occur during illness, accidents, or other unexpected events.

Excepted benefits products provide value to millions of Americans and the difference between excepted benefits and traditional health insurance has been acknowledged in federal law and regulation for over 25 years. Including excepted benefits in the scope of the rule will severely disrupt the market for these benefits, creating an unlevel playing field among health insurance providers who are subject to the rule and those that do not qualify as covered entities. Many excepted benefit products are guaranteed renewable and not underwritten annually. Certain products may have lines of business that may have completely closed to new enrollment, such as pre-standardized and standardized Medicare supplemental plans, and the disruption to those policyholders would be substantial. This disruption may drive competitors out of the market, ultimately increasing health care costs and reducing product choice for consumers. Additionally, while excepted benefits are discussed in the rule’s preamble, nothing in the proposed regulatory text explicitly addresses excepted benefits. We recommend HHS exclude excepted benefits from the scope of the final rule.

Third Party Administrators

Third party administrators (TPAs) provide administrative services for self-insured health plans and do not receive federal funds from HHS. Including TPAs in the scope of the rule will likewise create an unlevel playing field among health insurance providers who are subject to the rule and those that do not qualify as covered entities because they do not receive federal financial assistance or have legal structures that separate their TPA business. HHS should exclude TPAs from the scope of the final rule.

Grandfathered and Transitional Plans

Grandfathered plans and transitional plans are not subject to many of the ACA’s provisions and applying the Section 1557 rule to these plans could result in increased costs and

discontinued plans. The Centers for Medicare and Medicaid Services (CMS) has reiterated support for continuing grandfathered and transitional plans in the past, most recently in a March 2022 bulletin extending the non-enforcement policy for transitional plans that will remain in effect until further notice. For these reasons, grandfathered and transitional plans should be exempted from the scope of the final rule.

Recommendations:

- **Exclude excepted benefits from the scope of the final rule because excepted benefits are treated separately under the ACA and other laws, do not involve federal financial assistance, and including them in the final rule would lead to an unlevel playing field among health insurance providers.**
- **Exclude third-party administrators from the scope of the final rule because, similar to excepted benefits, including them in the final rule would lead to an unlevel playing field among health insurance providers.**
- **Exclude grandfathered plans and transitional plans from the scope of the final rule, for similar reasons.**

III. Compliance Obligations

Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)

HHS proposes that covered entities with 15 or more employees designate at least one employee to serve as a Section 1557 coordinator, with responsibilities including grievance procedures, recordkeeping, implementing language access, effective communication, reasonable modification procedures, and coordinating employee training.

Health insurance providers will operationalize 1557 coordinator activities in a variety of ways given the impact across large organizations spanning multiple lines of business and states. As such, it may be most appropriate to apply these responsibilities to existing offices or departments that oversee related issues. Given the time needed to review previous positions, descriptions, processes, requirements, and implement any changes as a result of the final rule, we recommend that HHS allow for additional flexibilities in how these requirements are operationalized. Requirements to list specific individual's name and contact information can raise privacy concerns as well as administrative burden when there are staffing changes, reorganizations, or turnover. HHS should clarify that the 1557 coordinator contact information may direct consumers to a specific job title, department, or office that handles Section 1557 duties rather than a specific individual. This will also promote continuity during transition periods, parental leave, vacations, or when the primary

coordinator is otherwise unavailable.

Additionally, HHS should clarify that the Section 1557 coordinator is responsible for oversight and that other staff may lead the implementation of various activities. We encourage HHS to add the phrase “or designee” after “Section 1557 Coordinator” in § 92.7 (b) to confirm that covered entities can assign one or more staff members to complete specific Section 1557 related functions.

Recommendation:

- **Clarify that the Section 1557 Coordinator can be listed as a job title or department function rather than an individual’s name, and they hold oversight responsibilities for Section 1557 policies and procedures.**

Policies and Procedures (§ 92.8)

HHS proposes requirements for covered entities to develop and implement written nondiscrimination, grievance, language access, auxiliary aids and services, and reasonable modification policies and procedures.

Creating and maintaining a list of specific staff and translated materials will be difficult for large organizations to update and access. Health insurance providers should have the option to provide the business rules and rationale, such as how and where documents are stored, rather than creating a duplicative process, and rely on interpretation or translation vendors who maintain records of employee certification.

We strongly recommend HHS streamline existing language requirements across programs to reduce administrative burden and promote more consistent procedures across health care programs. For health insurance providers that offer QHPs in the individual market, we recommend HHS reinstate requirements from the 2016 final rule at § 92.8 that compliance with Section 1557 rules will be deemed in compliance with cross-referenced Exchange and QHP requirements.³ This will ensure the broad goals are met without having slight variations

³ Regulatory text for taglines related to the Exchange is at 155.205(c)(2)(iii)(A):

(A) For Exchanges and QHP issuers, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. ...Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. ... A QHP issuer may aggregate the limited English proficient populations across all States served by the health insurance issuers within the issuer's controlled group (...), whether or not those health insurance issuers offer plans through the Exchange in each of those States, to determine the top 15 languages required for taglines. Exchanges and QHP issuers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any critical stand-alone document linked to or embedded in the Web site. Exchanges, and QHP

in compliance obligations. Following the final rule, we recommend HHS work with the Center for Consumer Information and Insurance Oversight (CCIIO) to update their regulations accordingly and that any related sample policies and procedures be flexible for health insurance providers to accurately describe their own business and compliance processes.

Recommendations:

- **Allow flexibility for health insurance providers to provide business processes and rationale that reduces duplication and maintains meaningful access and effective communication for LEP individuals and individuals with disabilities.**
- **Reinstate deeming approach for Section 1557 requirements and cross-referenced Exchange and QHP requirements.**

Training (§ 92.9)

HHS proposes that covered entities train relevant employees of their health programs and activities on Section 1557 and civil rights policies and procedures. HHS proposes relevant employees complete their training no later than one year after the rule's date of enactment and new employees do so within a reasonable period of time.

Additional time is needed for health insurance providers to develop, review, and execute new training programs for employees. We recommend HHS increase the timeline to complete this training from one year to 12 months, consistent with our earlier recommendation to extend the proposed rule's effective date. To reduce the administrative burden of these new training requirements, HHS should clarify that covered entities can incorporate Section 1557 training into existing annual compliance materials and requirements. This will provide additional efficiency to complete required training in a timely fashion. HHS should also provide optional guidance and resources that outline potential topics and other resources for Section 1557 training for covered entities that wish to utilize them.

Recommendation:

- **Allow covered entities 12 months to develop and complete Section 1557 training and clarify that Section 1557 training can be incorporated into existing annual compliance training.**

IV. Notice Requirements, Meaningful Access, and Effective Communication

Notice of Nondiscrimination (§ 92.10)

HHS proposes requirements for covered entities to provide a notice of nondiscrimination to participants, beneficiaries, enrollees, applicants, and members of the public relating to its health programs and activities on an annual basis and upon request.

AHIP supports requirements to provide the notice of nondiscrimination annually and appreciates HHS taking the scope and burden on health insurance providers into consideration when proposing these requirements. However, this requirement poses additional costs to commercial and Medicare Advantage plans and printing and mailing costs for commercial market plans that do not currently send out annual notices in a separate mailing. If new notice requirements are implemented mid-plan year, it will create additional operational burdens for state regulators to review and approve revised insurer forms and update their own state requirements where applicable. In circumstances where plans do not have a guaranteed annual mailing, HHS should permit the notice of nondiscrimination to be incorporated into the next mailed communication.

An increasing number of Americans rely on digital channels to receive information about their health plan. Allowing electronic delivery of the notice and other disclosures presents substantial consumer benefits beyond the reduction in burden to the health plan. Electronic communication can also reduce or eliminate the need for paper notices. By orienting more health plan communications through electronic channels where direct notification is possible, consumers can receive more actionable and timely information. Printing is a physical process that requires lead time to complete large quantities of information, such as annual renewal packets. Instead of tracking benefits across several different physical mailings, electronic communications give participants and beneficiaries the option of rapid, reliable, and streamlined access to their plan information — potentially increasing health literacy and engagement in their own health and reducing the environmental footprint of paper processes. All consumers should have meaningful access in a manner of their choosing, therefore there must remain a cost-free option for those who prefer paper disclosures. HHS should permit electronic communication in lieu of mailings where permitted by regulation and allow notices to be sent digitally with other communications.

Electronic communications would also expand the ease of language translation and enable consumers to more easily access the notice in their preferred language. Ensuring people understand their rights and responsibilities and have quick access to a qualified interpreter must be the stated goal of the language access policies. Reliance on translation of written materials should be only upon request. In addition to the costs and burden of translation, access to quick and efficient interpretation services can more accurately convey complex

insurance and medical terms in a culturally appropriate manner that LEP individuals can understand. HHS should allow the notice of nondiscrimination to be provided only in English as long as it is accompanied by the notice of availability, which includes language access information, similar to other plan communications. HHS also should clarify that in addition to the annual notices listed in the proposed rule, the notice of nondiscrimination may also be combined with annual required notices delivered to enrollees such as notices regarding Part D creditable coverage, the Children's Health Insurance Program (CHIP), and Women's Health and Cancer Rights Act (WHCRA).

Recommendations:

- **Support providing the notice of nondiscrimination annually at the time of initial enrollment, upon request, and prominently on individual and group health plans' websites.**
- **Clarify that the notice of nondiscrimination can be provided electronically in lieu of printed mailings, where permitted by regulation.**
- **Clarify that the notice of nondiscrimination may be provided in English if it is accompanied by the notice of availability of language assistance services and that it may be combined with other annual notices.**

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

HHS proposes requirements for covered entities to notify beneficiaries, enrollees, applicants of health programs or activities, and members of the public of availability of language assistance services and auxiliary aids and services. The notice of availability must be provided in English and the 15 most common languages spoken by LEP individuals of the relevant state and in alternate formats for individuals with disabilities. Notices must be provided on an annual basis, upon request, and with 10 significant communications as listed by HHS. HHS considered an alternative approach of limiting requirements to only Explanations of Benefits (EOBs) that notify individuals of cost-sharing responsibilities, and also proposes alternative approaches to comply with notice requirements. The alternative approaches include an annual opt-out and documentation of an individual's primary language or appropriate auxiliary aids and services.

AHIP and our health insurance provider members share HHS' commitment to ensuring that LEP individuals and individuals with disabilities can understand information provided by their health plan and access the care they need. We provide the following recommendations

to improve operational processes that balance cost and administrative burden while still connecting individuals with language services in the most effective way possible.

15 Most Common Languages

HHS proposes that notices must be provided in the 15 most common languages of the individuals of the relevant state. AHIP requests clarification that, similar to the 2016 rule, covered entities that operate in multiple states may aggregate the calculation of the top 15 languages for their entire service area or by individual state.

Significant Communications

AHIP appreciates the clarity of a specific list of significant communications with which HHS would require health insurance providers to provide the notice of availability, but remains concerned about the frequency, length, cost, and administrative burden of producing the required notices. Including these notices with nearly every health insurance provider communication also increases consumer confusion and overwhelms individuals with information that may not meet their specific needs.

AHIP recommends two approaches to narrowing the number of significant communications subject to the proposed rule's requirements: 1) HHS should consider whether including a reference to where the notice of availability can be found in contracts, e.g., a member handbook or enrollment materials, similar to grievance and appeals and claims provisions, would be more useful to consumers and reduce unnecessary paperwork; and 2) Required notice materials regarding language access and effective communication for individuals with disabilities should be as concise as possible and limited to essential information for individuals who access these services.

While not every health insurance provider may be able to operationalize and administer a process to differentiate EOBs with or without cost-sharing requirements, HHS should also finalize the option for health insurance providers to only include the notice of availability with EOBs that notify individuals of a cost-sharing responsibility. EOBs are the most frequent communication in which consumers would receive the notice of availability and giving health insurance providers the option to only include the notice of availability with EOBs that have financial implications for enrollees will limit the requirements to the most necessary instances. Similar to the 2016 rule, HHS should also permit covered entities to include a single set of taglines for a mailing if the mailing includes more than one of the specified documents.

Small-sized Communications

Requiring translated notices in multiple languages results in many additional pages and, particularly for small communications, can overwhelm and confuse consumers who may be searching for language access information. In the 2016 rule, HHS previously permitted

small-sized communications such as postcards, brochures, and pamphlets, to include at least a nondiscrimination statement in English and taglines in the top two languages spoken by individuals with LEP in the state. HHS should reinstate this requirement in the final rule to provide additional flexibility and more meaningful communication for small-sized communications. HHS should also clarify that marketing materials may be considered small-sized communications for these purposes. Following the final rule, CMS should provide additional guidance for states on how to harmonize Section 1557 requirements with existing Medicaid requirements.

Alternative Approaches

AHIP appreciates HHS' consideration of alternative approaches for opt-out and language preference tracking and supports the inclusion of these options. Language preference tracking has the potential to provide more personalized resources to enrollees rather than general notices and information. This could include a single preferred language tagline, potentially in a much larger range of languages than the top 15 languages, tailored resources specific individuals may need, or preferred methods of communication. HHS should ensure that these approaches remain optional. HHS should also work with other agencies, including CMS, to leverage existing processes and accommodate any necessary technical changes to standard HIPAA standardized enrollment transaction fields to ensure that language preference tracking option can be as streamlined and integrated as possible. Health insurance providers should respect enrollees' preferences without requiring them to actively renew their preferences each year. Additionally, HHS should accept, but not require, the selection of English as a primary language in the 834 enrollment transaction as an affirmative opt-out for purposes of the notice of availability.

HHS should also clarify that the proposed alternative approaches can be combined with the notice of availability to achieve compliance. For example, if a plan chooses to provide notices or communications in Spanish for individuals who select that as their language preference, they should still be able to provide the notice of availability in English and top 15 languages for individuals with other language preferences. Finally, HHS should provide flexibility for electronic access or delivery, such as website links or QR codes, emails, or texts, for enrollees opted-in to digital channels. This will further reduce the need to provide paper notices with plan communications.

Universal Language Access Symbol

We recommend HHS convene a robust stakeholder process to develop, test, and pilot use of an easy-to-understand universal language access symbol to connect LEP individuals with

language services as an alternative to notice requirements, similar to the National Interpreter Symbol currently used by Australia.⁴

The symbol would include a character icon that is widely understood to indicate language access as well as a phone number that connects people directly with language services. We applaud the Office of Minority Health’s study of this area and encourage HHS to expand their focus to eventually pursue a long-term stakeholder process that incorporates listening sessions, industry collaboration, pilot programs, and notice-and-comment rulemaking to develop a universal language access symbol that provides value to consumers, increases the accessibility of language services, and reduces unnecessary administrative burden and wasteful paper notices. Adoption of a language access symbol may provide easier-to-access translation services at a lower administrative cost.



Figure 1: Illustrative Example of Universal Language Access Symbol

Recommendations:

- **Allow covered entities to calculate the 15 most common languages in a relevant state by aggregating their entire service area or by individual state.**
- **Streamline the number of significant communications with which health insurance providers are required to provide the notice of availability.**
- **Include the “small-sized” communication provision from the 2016 final rule in the revised Section 1557 final rule and provide additional guidance to states on harmonizing Medicaid requirements.**
- **Support HHS’ alternative approaches for opt-out and language preference tracking, ensure that they remain optional, and leverage existing standardized HIPAA transactions.**
- **Work with stakeholders to develop alternative approaches to connect LEP individuals with language access services, including adoption of a universal language access symbol.**

⁴ [National interpreter symbol](#) | [For government Resources](#) | [Queensland Government](#)

Meaningful Access for Limited English Proficient Individuals (§ 92.201)

HHS proposes requirements for covered entities to provide meaningful access to each LEP eligible to be served or likely to be directly affected by its health programs and activities, including language services such as interpretation and translation services.

In AHIP's recent survey of its health insurance providers that offer coverage in the commercial market discussed in more detail in Section VI of our comments, respondents provided examples of the many language access services available. Each service provides different value to enrollees and specific services including interpretation, translation, in-person events, personal outreach, and others are appropriate in different settings. Some health insurance providers provide audio files, language-specific websites, or in-person or remote video interpreters for certain provider visits for LEP individuals and conduct cultural competency training courses and resources for staff, including health equity topics and proper interpreter use.

Health insurance providers utilize interpretation to convey complex medical and insurance terminology in a culturally competent manner and address enrollee questions in real time. Translations cannot always accurately convey the meaning and nuance of insurance terms and can be easily misunderstood. As required by the APA, HHS should consider, and account for, information such as AHIP's survey, indicating that regulatory flexibility allows health insurance providers to develop innovative and beneficial information to LEP individuals. HHS should maintain regulatory flexibility to develop meaningful access for LEP consumers that focuses on quick and streamlined access to interpretation with written translations only provided upon request.

Recommendation:

- **Support maintaining ability for health insurance providers to develop meaningful language access for LEP consumers that incorporates a variety of innovative approaches and services.**

Effective Communication for Individuals with Disabilities (§ 92.202)

HHS proposes requirements for covered entities to take appropriate steps to ensure effective communication with individuals with disabilities and companions with disabilities, including providing appropriate auxiliary aids and services when necessary.

In AHIP's recent survey, member health insurance providers also described various methods they offer for effective communication for individuals with disabilities. As above, HHS should, under the APA, account for this information in its rulemaking. Plans provide audio files, large print, braille, and sign language communications, as well as innovative digital

formats. Similar to the recommendation on meaningful access, HHS should maintain regulatory flexibility to develop effective communication with individuals with disabilities and companions with disabilities that focuses on access and not prescribing specific methods of communication.

Recommendation:

- **Support maintaining ability for health insurance providers to develop effective communication methods for individuals and companions with disabilities.**

Accessibility of Information and Communication Technology for Individuals with Disabilities (§ 92.204)

HHS proposes requirements for covered entities to ensure that their health programs and activities provided through information and communication technology (ICT) are accessible to individuals with disabilities unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of health programs or activities.

Web Content Accessibility Guidelines (WCAG) is a widely known, published standard that is updated on a regular basis. Covered entities should not be required to adopt these standards, but HHS should affirm that compliance with WCAG 2.1 Level AA should be considered as meeting the applicable requirements under the proposed rule.

Recommendation:

- **Deem covered entities that are in compliance with Web Content Accessibility Guidelines (WCAG) 2.1 Level AA as being in compliance with Section 1557.**

V. Other Provisions

Nondiscrimination in Health Insurance and Other Health-related Coverage (§ 92.207)

Integrated Care Settings for Individuals with Disabilities

HHS proposes prohibiting covered entities from having or implementing benefit designs that do not provide care in the most integrated setting appropriate for individuals with disabilities or put individuals with disabilities at risk of placement within an institution, congregate care setting, or other segregated settings.

AHIP supports ensuring that individuals with disabilities receive integrated care wherever possible. When implementing this provision, HHS should ensure that clinically appropriate use of benefit design and medical management tools such as prior authorization or step therapy are still allowed. For example, in many institutional settings, patients are closely

monitored by medical professionals and medical management may not be necessary in the same way as in community or home-based settings. In addition, in some instances, state Medicaid requirements may conflict with the proposed rule. For example, some states capitate Medicaid managed care plans for care in long-term care facilities but exclude coverage of home- and community-based services (HCBS) in managed care contracts. In such cases, Medicaid plans are acting at the state's direction to implement some but not all of the long-term care components of the state's approved Medicaid plan. We are concerned that under the proposed rule, a Medicaid plan could be viewed as not providing care in the most integrated setting, even though it is doing so at the state's direction under the state's Medicaid plan approved by the federal government. We recommend that HHS exempt Medicaid plans from integrated care requirements when they are acting at the direction of a state.

Recommendations:

- **Support provision of services in the most integrated setting possible provided that the current benefit design is clinically appropriate and implementation practices would not fundamentally alter the nature of the service, program, or activity.**
- **Exempt Medicaid plans from integrated care requirements acting at the direction of a state.**

Medical Necessity, Medical Management, and Utilization Management

HHS clarifies that nothing in the proposed rule requires coverage of any health service where there is a legitimate, nondiscriminatory reason for coverage limitations, including medical necessity, medical management, utilization management techniques based on clinical standards and evidence-based guidelines that are applied in a neutral, nondiscriminatory manner.

Medical management tools provide an important role in promoting quality care and reducing health care costs. AHIP supports this clarification and encourages HHS to finalize this provision.

Recommendation:

- **Support HHS' clarification that medical management based on clinical evidence is permitted, including the use of reasonable medical necessity and utilization management techniques based on clinical standards and evidence-based guidelines that are applied in a neutral manner.**

Benefit Design

AHIP shares the goal of ensuring that health insurance coverage protects against

discrimination. HHS should establish clear, fact-based criteria for compliance that include predictable standards that can be implemented by health insurance providers and is not solely focused on retroactive evaluations. For example, health insurance providers already incorporate clinically-based evidence into benefit design through recommendations and guidelines from the U.S. Preventive Services Task Force (USPSTF) and other relevant entities, as well as medical review and exceptions processes to ensure that individuals can access the care that they need. Benefit design can also encourage those with chronic diseases to engage in care by, for example, lowering costs for prescription drugs or certain provider visit copays. If finalized as proposed, we are concerned that some of these programs would be reconsidered due to potential interaction with Section 1557 nondiscrimination provisions. HHS should coordinate their activity with other agencies, such as CMS, that establish specific plan requirements and approval processes and defer enforcement action to existing review processes where appropriate.

HHS mentions that there are specific instances where state law or benefit mandates may be considered discriminatory. HHS should establish a safe harbor for health insurance providers to comply with Section 1557 standards in cases where there are state law interactions to avoid creating multiple or duplicative standards. This should include providing clarity on the interaction between the Section 1557 requirement and the 2023 Notice of Benefit and Payment Parameters final rule regarding non-discriminatory benefit design and Essential Health Benefits.⁵ We note that required benefits are regulated by the federal government in Medicare (i.e., Medicare Advantage plans are required to cover benefits covered by original Medicare) and Medicaid (Medicaid managed care plans follow state requirements). For the individual and small group markets plans are required to cover essential health benefits selected by their respective state. Any regulatory requirements should not require coverage of additional benefits beyond the stated requirements.

Finally, HHS proposes that TPAs may be liable under this part when they are responsible for the underlying discriminatory plan design feature adopted by a group health plan. This contrasts with the 2016 rule where the party responsible for the discriminatory design was liable. HHS should clarify that administrative actions such as developing documents or preparing policy booklets for clients would not constitute TPA liability for discriminatory plan design features.

Recommendations:

- **Establish a forward-looking regulatory framework that sets clear standards and criteria for compliance and discourages retroactive penalties.**

⁵ 87 FR 27208

- **Create a safe harbor for state laws and benefit mandates and provide guidance on how health insurance providers should comply.**
- **Ensure that the final rule does not obligate coverage of additional benefits beyond federal and/or state requirements.**
- **Clarify that TPA administrative actions are not liable for discriminatory plan design features.**

Network Adequacy

HHS states that establishing uniform or minimum network adequacy standards is outside the scope of this rule, but certain instances where provider networks exclude or limit access to certain providers may raise discrimination concerns. HHS requested comment on how Section 1557 might apply to provider networks and how provider networks are developed, including factors that are considered in the creation of the network and steps taken to ensure an adequate number of providers and facilities.⁶

Health insurance providers create robust provider networks that provide high quality care and deliver value to their members. High quality provider networks are designed in response to consumer needs and promote access to quality care, lower costs, and increase competition among plans and providers.

As part of the network development process, plans create innovative network and benefit structures to best meet consumer preferences and priorities. Networks meet specific safety, quality, and performance standards, and help reduce premiums and promote affordable coverage options. Provider networks include a variety of primary care doctors, specialists, hospitals, and other facilities so consumers can access care when and where they need it. Plans also comply with requirements to contract with providers that work with underserved, high-risk, or special needs populations.

Networks depend on nuances of local communities, including geographic features, hospital and provider availability, health care markets, and other unique factors that can vary by location. Additionally, care delivery patterns continue to shift over the course of the COVID-19 pandemic and eventual wind-down of the public health emergency. Patients and providers continue to seek technology solutions and telehealth options for providing and receiving care. This can also promote access to consumers in rural areas, areas with provider shortages, or when particular specialty care or expertise is necessary.

Another factor that influences network development is provider contracting practices,

⁶ 87 FR 47878

particularly among hospital systems. Provider contracting practices such as “all-or-nothing” contracting and anti-tiering clauses harm consumers by increasing provider leverage and driving up health care costs. As network requirements increase, providers and facilities use these rules to demand increased rates, additional contracts for other member or system facilities, and specific network tier placement. Consistent with our previous recommendations, we encourage HHS to consider ways to limit these practices and provide additional flexibility in these circumstances.

Many organizations and agencies including CMS, states, the National Association of Insurance Commissioners (NAIC), and accreditation entities such as Utilization Review Accreditation Commission (URAC) and the National Committee for Quality Assurance (NCQA) have existing network adequacy standards that plans are subject to or rely on for developing access, depending on the market. Network adequacy is regulated directly at the state and federal levels, and existing standards for Exchanges, Medicare Advantage, Medicaid, and other plans incorporate understanding of local provider availability, geographic areas, and market-specific conditions. To avoid duplicative review processes, HHS should defer any concerns about provider networks and network adequacy to the appropriate state or federal agency and rely on their existing standards and approval processes to ensure that consumers have robust access to care.

Recommendation:

- **Affirm that network adequacy is outside the scope of the Section 1557 rule and should continue to be regulated directly by relevant state and federal agencies.**

Clinical Algorithms (§ 92.210)

HHS proposes requirements that covered entities must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision making. HHS does not propose a formal definition of clinical algorithms, but generally describes clinical algorithms as tools used to guide health care decision-making including flowcharts, decision support, models, and other tools.

AHIP strongly supports the proposed rule’s goal of nondiscrimination. However, the general application of nondiscrimination to covered entities under Section 1557 already prohibits discrimination in health programs and activities, and this section may unintentionally duplicate those provisions. Broad or unclear definitions could inadvertently create confusion and unintended regulatory compliance issues. While the use of clinical algorithms has long been part of the standard of care in medicine, the potential for bias has come to the forefront as more data sources have become available, the interoperability of that data has increased, and machine-learning techniques have been applied. This advancement in data and analytics has both uncovered existing biases in data sets and clinical algorithms as well as created new

biases in some contexts with the implementation of novel computational methods. There is unanimity in the healthcare system that we must ferret out and mitigate such biases, but we are still in the early stages of being able to do so.

As we note in our comments on data collection, to detect bias we must first collect accurate, standardized demographic data, and AHIP is playing a leadership role in advancing this effort. To successfully mitigate bias, we cannot ignore factors such as race, sex, disability or other protected classes. Instead, we must incorporate them and scrutinize the potential for differential impacts associated with our analytical and/or programmatic decisions on the health and health care outcomes of these populations. We agree with HHS that it can be appropriate and justified to integrate such demographic factors in clinical algorithms to “...identify, evaluate, and address health disparities.”⁷ Any guidance or requirements should be clear that covered entities can seek what is sometimes referred to as “good bias” – which broadly means that data, analytics, and clinical programs can be designed and adjusted to benefit certain populations to overcome disparities in health and health care.

HHS should seek policy solutions that balance promising innovations and the potential for risk. We know there will be unintended consequences and cannot second guess all the pitfalls, but we can create a system that closely monitors for problems, nimbly addresses them, and does so in a transparent fashion. To that end, AHIP has been working with the Consumer Technology Association and others to promote education, awareness, and industry adoption of common definitions, key constructs, and standards for Artificial Intelligence (AI) including machine-learning algorithms. Our collaboration includes the development of standards to promote trust in healthcare, such as ensuring the transparency and explainability of data and methods and will soon culminate in a standard for risk management and bias.⁸ While HHS notes that the focus of its proposal is on clinical algorithms and not general applications of what it calls “augmented intelligence”, much of this industry-led effort is and will be applicable. Rather than moving forward with additional regulation, we believe HHS should leverage this work to further educate and inform covered entities.

We also note that there is already significant activity at the state and federal level in this area. Examples include the National Institute of Standards and Technology (NIST) and the comprehensive and ongoing body of work related to AI and mitigating risk and adverse bias in AI-based algorithms. The Federal Trade Commission (FTC) has also released comprehensive guidance on this topic as the Commission seeks to promote truth, fairness and

⁷ 87 FR 47,881

⁸ More information is available at: <https://www.cta.tech/Resources/Newsroom/Media-Releases/2021/February/CTA-Launches-New-Trustworthiness-Standard-for-AI-i>

equity in AI-based algorithms using existing legal requirements and agency authority.⁹ HHS should allow NIST, the FTC, and others to be the primary federal leaders in this area.

We recommend HHS not move forward with additional regulations at this time. However, if HHS pursues additional regulations in this area in the future, it should first solicit additional input from stakeholders to gather information about the development and use of clinical algorithms as well as industry efforts to mitigate bias. In addition, it should establish a clear definition of the clinical algorithms used for care delivery to which such a policy would apply. Specifically, the definition should make clear that the policy is applicable to only the underlying clinical decision-making algorithms and neither to the financial, actuarial, and other insurance processes that encompass health insurance providers' business functions nor the broader construct of artificial or augmented intelligence. Finally, if HHS chooses to move forward with this proposal immediately, it should deem entities in compliance if they have established processes to test algorithms for bias before implementation and regularly audit for any unintended consequences after implementation.

Recommendation:

- **Do not finalize provisions related to clinical algorithms at this time and convene a stakeholder process to gather additional input about the use and application of these tools.**

Nondiscrimination in the Delivery of Health Programs and Activities through Telehealth (§ 92.211)

HHS proposes requirements that covered entities must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through telehealth services, including accessibility of telehealth platforms, providing effective communication for individuals with disabilities and language assistance services for LEP individuals.

Particularly during the COVID-19 pandemic, the use of telehealth has increased dramatically and provides significant value to consumers. While in-person services may be necessary in certain situations, telehealth can promote greater access, particularly for specialty care or in rural areas or locations experiencing significant provider shortages.

As mentioned under § 92.204, we support a deeming approach for covered entities in compliance with WCAG 2.1 Level AA as being in compliance with Section 1557. Covered entities should not be required to adopt these standards, but HHS should affirm that compliance with WCAG 2.1 Level AA should be considered as meeting the applicable

⁹ More information is available at: <https://www.ftc.gov/business-guidance/blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai>

requirements under the proposed rule.

Recommendations:

- **Support the expanded use of telehealth services as a critical access tool and growing area of care delivery.**
- **Deem covered entities that are in compliance with Web Content Accessibility Guidelines (WCAG) 2.1 Level AA as being in compliance with Section 1557.**

Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

HHS proposes new procedures for notification and application of federal conscience and religious freedom laws and will approach determinations on a case-by-case basis.

We recommend the final rule clarify the relationship between Section 1557 nondiscrimination requirements and employer and provider religious and conscientious freedom rights. This is particularly important if the final rule includes a covered entity's TPA operations within the scope of the rule. Specifically, HHS should clarify that a health insurance provider or TPA is not in violation of the final rule if an employer that offers coverage or a provider within the covered entity's network exercises conscientious or religious objections that are protected under federal or state law.

When employers claim that federal conscience and religious freedom laws apply, there are implications for health insurance providers that are covered entities that require additional clarification in the final rule. We recommend as a general matter, health insurance providers are not required to offer benefits packages that meet all possible combinations of employer preferences or are customized to each employer's unique views. However, we recognize that employers may opt-out due to conscience or religious freedom objections. If a covered entity is found to be exempt from a provision of Section 1557 due to a conscience or religious freedom objection, a health insurance provider or TPA is not in violation of Section 1557 if they administer benefits on behalf of that covered entity consistently with the entity exercising their conscientious or religious freedom rights. Finally, HHS should clarify that a health insurance provider or TPA is not in violation of Section 1557 if they include a covered entity that has exercised a conscience or religious freedom right in their provider network.

Recommendations:

- **Clarify that a health insurance provider or TPA does not violate Section 1557 if an employer that offers coverage or a provider within the covered entity's network exercises conscience or religious freedom objections that are protected under federal or state law.**

- **Ensure that health insurance providers are not required to offer customized benefits or benefit packages that meet all possible employer preferences and that offering benefit packages without certain services for employers that opt-out does not violate Section 1557.**
- **Affirm that health insurance providers or TPAs that administer benefits on behalf of a covered entity that exempt from a provision of Section 1557 or include providers who exercise a conscience or religious freedom right as part of their network are not in violation of Section 1557.**

VI. Requests for Comment

As part of the multiple requests for comment included in the proposed rule, AHIP is providing additional feedback on the costs related to the notice requirements and data collection.

Costs Related to Notice Requirements

In November 2021, AHIP surveyed its commercial health insurance provider members on the cost and utilization of notice and tagline requirements. Seventeen health insurance providers in the commercial market, representing over 110 million covered lives, reported on their current initiatives to provide meaningful access to appropriate language access services.

AHIP found that on average, the health insurance providers surveyed mail over 34 million tagline notices per year, with individual enrollees receiving an average of 6.2 taglines per year. Tagline production cost these health insurance providers, on average, over \$2 million annually and up to \$8.91 per member per month.

Most importantly, in the over five years since the notice and tagline requirements were originally adopted, there has not been a measurable increase in requests for language services or a corresponding decrease following the finalization of the 2020 rule's provisions, indicating that LEP individuals in the most need of these services may not be effectively reached by notice requirements. We encourage HHS to work with health insurance providers and other stakeholders to evaluate alternative methods, such as the universal language access symbol, to improve access to language services and reduce repetitive and ineffective paper notices.

Data Collection

HHS does not propose data collection requirements but seeks comment on approach and use

of data collection efforts.¹⁰ Specifically, HHS seeks comment on general data collection approaches, the current status of data collection, necessary requirements and types of data, relevant definitions, and potential costs and benefits associated with data collection requirements.

Achieving health equity is a priority for AHIP and our health insurance provider members. We take our responsibilities to improve health equity seriously and believe in the importance of having demographic data to better detect disparities in care and outcomes, address social determinants of health, and promote equitable care. We understand that to address health inequities, accurate data is needed to know where disparities exist to inform effective solutions that take cultural preferences and socioeconomic circumstances into account. However, we ask that HHS, regulators, and policymakers consider the current barriers to collecting these data, including the importance of personal agency in providing sensitive information on one's identity.

For health insurance providers, there are four pathways to directly collect demographic data: 1) collection at enrollment; 2) surveying members or other outreach methods; 3) obtaining the data from providers as part of a claim or from the electronic health record (EHR); and 4) obtaining demographic data from employers or government agencies that collect it.

Key challenges with data collection include:

- **Statutory Barriers:** Several states such as Maryland, California, New Jersey, and New Hampshire have, or at one point had, laws barring the collection of race and ethnicity data on applications for insurance over concerns of this data being used to determine eligibility for benefits. In addition, state policymakers are currently contemplating legislation that would further impede health insurance providers' ability to collect data. For example, Colorado has pending legislation, SB21-169, which would prohibit the use of certain protected class information "in any insurance practice."
- **Regulatory Barriers:** Policies and procedures required by governing agencies (e.g., the state-level Departments of Insurance) make it difficult to revise enrollment forms so that health plans can collect racial and ethnic data.
- **Employer Health Plan Sponsor Barriers:** Many employers may be hesitant to update enrollment forms or to ask employees to provide this data for insurance enrollment. Additionally, some employers do not allow insurers to reach out to their employees to collect demographic data.
- **HIPAA Transaction Standards:** The HIPAA-prescribed 834 enrollment transaction form does not require the inclusion of demographic codes leading to incomplete data

¹⁰ 87 FR 47,856

provided to insurers. Claims data is similarly limited by the HIPAA-prescribed 837 claims transaction forms that do not require use of demographic codes.

- **Negative Member Response to Data Collection:** Survey data is often met by negative member reaction and response to such data collection. There may be a perception of potential discrimination for benefit eligibility, distrust, and lack of understanding of the purpose for collection. Other considerations include difficulties in successful outreach due to issues such as member enrollment/disenrollment (sometimes referred to as “churn”) and frequent changes in address.
- **Interoperability Challenges:** EHR data is not routinely shared with plans unless attached to claims. Interoperability issues may also impede the sharing of data between plans and providers given lack of data standards and the use of different codification structures.
- **Community Trust:** Underscoring all these challenges is the need to address issues of trust among consumers about the collection and sharing of potentially sensitive data between employers, clinicians, and health insurance providers. While we agree that sharing personal information should remain voluntary for individuals to maintain their agency (or to have a “I choose not to respond” response choice so that individuals have an option to not disclose their personal information), voluntary data collection can inhibit efforts to have complete data on populations that may be required to maintain accreditations or to meet other standards set by CMS, state Medicaid agencies, or state regulations.

Another major consideration with self-reported demographic data collection is ensuring there are appropriate privacy protections across the entire process of data collection, reporting, and data sharing to avoid the risk of discrimination. For example, organizations should have appropriate policies for privacy, data sharing, data governance, and data breach in line with the HIPAA and the *Health Information Technology for Economic and Clinical Health Act* (HITECH) requirements. Organizations that are not regulated by HIPAA or HITECH should be governed by these requirements or requirements under a similar regulatory framework (e.g., the Federal Trade Commission regulating entities with “HIPAA-like” requirements). Informing care, population health management, and quality measurement are important functions that should occur with appropriate protection and security of sociodemographic data.

Another major challenge with data collection is the lack of alignment on demographic data standards across the health care ecosystem (whether across federal programs, markets, states, accreditation programs, and health care entities). This lack of alignment leads to fragmentation, duplication, and lower effectiveness of data collection overall.

Accurate, actionable, and standardized demographic data is foundational to advance health equity. Accurate demographic data will allow health care entities to better understand the populations they serve and to inform more culturally and linguistically appropriate care. It will also allow health care entities to better identify disparities, measure effectiveness of interventions, and ultimately address inequities. Standardized demographic data must be aligned at an ecosystem level across the greater public and private health care ecosystem to facilitate interoperable data sharing, aggregation, and collaboration, which is necessary to truly advance health equity.

Current data standards, whether from the Office of Management and Budget, CMS, the 2020 Census, or the 2011 HHS recommendations proposed in the ACA, still lead to inaccurate data and large amounts of “other” or “unknown” data, which hinder efforts to better understand populations served and reduce the disparities that different populations experience.

To improve upon existing demographic data standards, AHIP convened diverse groups of stakeholders for over eighteen months from 2020 – 2022 and employed an evidence-based and stakeholder-driven process to develop demographic data standards for race, ethnicity, language preference, sexual orientation, gender, disability status, veteran status, and spiritual beliefs. We welcome the opportunity to share this work and our findings that have been outlined in previous recommendations with HHS to further inform this effort. We stand ready to work with HHS, alongside consumers, policymakers, providers and employers to help stakeholders understand why this data is being collected, how it will be used, and the need to remove policy and operational barriers to better understand healthcare disparities.

We also encourage HHS to join us in developing frameworks, guidance, and best practices to help health care entities collect demographic data at scale in patient-centered and respectful ways, and how best to earn trust with individuals and communities given the cultural legacies of mistrust that will continue to make this a long-term but important undertaking. HHS should approach the collection and use of demographic data carefully so that this information is not used to perpetuate or create inequities as governing Administrations change over time. Agencies should embed equity in rules and regulatory text as opposed to simply in the introductory frameworks.

Additionally, HHS should broadly focus data collection on aligning demographic data standards and collection requirements, reducing reporting burdens, and improving response options and other flaws that make data less actionable. HHS should, under the APA, carefully consider and account for the AHIP points and research referenced above in its rulemaking, and similarly should consider the costs and benefits associated with potential approaches. Data collection efforts should also consider implications of potentially sensitive information, which should be collected in a trusted relationship with clear purpose and

conducted with appropriate analysis, review, and utilization processes. Any future data collection requirements should incorporate existing efforts and be developed in consultation with relevant stakeholders to ensure that they are measuring and achieving intended goals and purposes.

Recommendations:

- **Continue agency and stakeholder engagement process to improve data collection and promote health equity.**
- **Align demographic data standards across programs through federal policy changes that support standardized and interoperable data standards.**
- **Use an incremental phased approach with data collection: Start with just a few demographic data elements with interoperable codes and add additional data elements in subsequent years so that data collection entities can overcome data collection challenges while also helping avoid data burden on key stakeholders—including individuals who would be providing this sensitive information on their identities.**