799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

Vizient Office of Public Policy and Government Relations

Nondiscrimination in Health Programs and Activities (HHS-OS-2022-0012)

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Summary

On August 4, 2022, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) issued a proposed rule, "Nondiscrimination in Health Programs and Activities", to update regulations implementing Section 1557 of the Affordable Care Act (ACA) (hereinafter "Proposed Rule"). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in a health program or activity which receives any Federal financial assistance. Among other changes, the Proposed Rule expands the definition of discrimination on the basis of sex, requires covered entities (e.g., hospitals that receive Federal financial assistance) to implement and train staff on formal nondiscrimination policies and procedures, discusses notice requirements for nondiscrimination policies, prohibits discrimination in clinical algorithms, and explicitly includes telehealth services in nondiscrimination policies.

Comments are due **October 3, 2022** with provisions in the Final Rule expected to go into effect 60 days after it is released.

Background

The Office for Civil Rights (OCR) under HHS issued implementing rules on Section 1557 in 2016 addressing a wide range of topics from meaningful access for individuals with limited English proficiency (LEP) to definitions of "health program or activity" and "on the basis of sex."

Section 1557 incorporates its grounds for discrimination from other civil rights laws, including Title VI of the Civil Rights Act of 1964 (Title VI), Section 504 of the Rehabilitation Act of 1973 (Section 504), Title IX of the Education Amendments of 1972 (Title IX), and the Age Discrimination Act of 1975 (Age Act). Notably, Section 1557 does not apply to discrimination based on religion.

In August 2016, a lawsuit was filed challenging the rule's definition of discrimination on the basis of sex which included discrimination based on "gender identity" and "termination of pregnancy." A court in the Northern District of Texas issued a nationwide injunction prohibiting OCR from enforcing the parts of Section 1557 related to these interpretations of "on the basis of sex" finding that they violated the Administrative Procedure Act and the Religious Freedom Restoration Act. This lawsuit was remanded back to OCR for further consideration in October 2019 while OCR drafted a new rule.

In June 2020, HHS issued a new rule that eliminated several major requirements of the 2016 rule, including several language access requirements and enforcement requirements, and responded to the litigation about the interpretation of "on the basis of sex." The new rule also applied to a narrower group of HHS programs and health insurers. Additional lawsuits were filed but have been on hold pending the release of the Proposed Rule.

The Proposed Rule seeks to reinstate many of the provisions established in the 2016 rule, update definitions to incorporate new case law, and expand interpretation of some protections established in the law. Notably, the Proposed Rule expands applicability of the rule to Medicare Part B providers, adds a prohibition on discriminating based on marital, family, or parental status, and includes prohibitions on discrimination in clinical algorithms and telehealth.

Scope of the Proposed Rule

HHS proposes to apply the provisions of this rule to: (1) every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department of Health and Human Services (HHS); (2) every health program or activity administered by HHS; and (3) every program or activity administered by a Title I entity. This is broader than the application defined in the 2020 final rule, which limited application to only programs and activities administered by HHS under Title I of the ACA.[1]

HHS clarifies that the Proposed Rule, if finalized, would not apply to an employer's employment practices, including the provision of employee health benefits. HHS proposes that complaints alleging discrimination by an employer, such as those relating to the Federal Employee Health Benefits plan, will continue to be referred to the agencies that have jurisdiction over these complaints (i.e., the Equal Employment Opportunity Commission of Office of Personnel Management). HHS believes this will minimize confusion among individuals who seek to file a complaint. However, HHS will have jurisdiction over complaints alleging discrimination in covered health insurance or other health-related coverage. **HHS seeks comments on the effect of the proposed scope of application.**

Relationship to Other Laws

Section 1557 provides that "an individual shall not, on the ground prohibited under" Title VI, Title IX, the Age Act and Section 504 "be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." Consistent with the statute, HHS states that nothing in this rule should be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under Federal civil rights laws, Federal conscience or religious freedom laws.

Title IX Exceptions

In the Proposed Rule, HHS provides additional information regarding the interaction between Section 1557 and Title IX. Generally, the language in Title IX provides a basic prohibition on discrimination on the basis of sex and is applied in the education sector. One section of Title IX enumerates several circumstances in which the prohibition does not apply, which are commonly known as the Title IX exceptions.[2] The 2016 Final Rule did not incorporate these exceptions into Section 1557, but the 2020 Final Rule did. Going forward, HHS proposes to decline the interpretation in the 2020 Final Rule and exclude these exceptions. HHS reasons that the exceptions enumerated in Title IX are most often applied in the educational setting, which is significantly different than the healthcare setting. Further, incorporating these exceptions may lead to a delay in care or an inability to receive care because of a lack of facility options. HHS notes that it recognizes the importance of religious freedom, which is included in Title IX, but proposes not to

[1] Entities established under Title I of the ACA include federal and state health insurance marketplaces.

[2] These exceptions include admissions decisions of educational institutions, membership practices of certain tax-exempt social fraternities and sororities, and groups such as the YMCA/YWCA and the Boys and Girl Scouts. In addition to finding none of the exceptions particularly relevant to the healthcare setting, HHS enumerates concerns that could arise from attempting to integrate these exceptions into the healthcare setting. For example, HHS notes that impacted parties are often not able to choose where or from whom they receive care. Whereas students and families typically make a choice to attend religious educational institutions, patients seeking health care are much more likely to be driven by considerations of availability, convenience, urgency, geography, cost, insurance network restrictions, and other factors unrelated to the question of whether the health care provider is controlled by or affiliated with a religious organization.

incorporate Title IX's religious exceptions. HHS proposes instead to apply the legal standards articulated in the Religious Freedom Restoration Act (RFRA) and other similar religious freedom and conscience laws. **HHS requests comments on this approach.**

Definitions

HHS proposes to update and add a definitions section to the rule to provide more clarity for compliance. The 2016 Final Rule contained a dedicated definitions section, whereas the 2020 Final Rule repealed the definitions established in the 2016 Final Rule and, instead, relied on HHS regulations for the underlying civil rights statutes when enforcing Section 1557. HHS proposes to reincorporate many of the definitions from the 2016 Final Rule with a few updates as described below.

HHS proposes to define and update a range of terms related to language access, including limited English proficient (LEP) individuals; language assistance services; qualified bilingual/multilingual staff; qualified interpreter for a limited English proficient individual; and qualified translator. These definitions appeared in the 2016 Final Rule's definition section and have not been changed substantively. For example, HHS made minor adjustments to update the term "limited English proficient individual" to reflect the currently used terminology and expanded the definition of "limited English proficient individual" to clarify that an individual may be competent in English for certain types of communications (e.g., speaking) but not others (e.g., reading). **HHS welcomes comment on this proposal.**

Federal Financial Assistance[3]

HHS proposes to include the definition of Federal financial assistance to include grants, loans, and other types of assistance from the Federal Government, in accordance with the definition of the term in Section 504 and the Age Act implementing regulations. Examples of HHS programs that provide Federal financial assistance subject to this part include Medicaid and CHIP, Medicare Part A, Medicare Part C, Medicare Part D, and HHS grant programs. Notably, HHS also includes a proposal to include Medicare Part B as a form of Federal financial assistance.

Medicare Part B was not previously considered a form of Federal financial assistance. This is because Medicare Part B funds are intended to subsidize healthcare providers and suppliers for the services and supplies rendered to program beneficiaries. In the Proposed Rule, HHS notes that Medicare Part B has evolved into a program similar to Medicare Part A, and thus should now be considered a form of federal financial assistance.

HHS clarifies that the Proposed Rule would only apply to entities receiving Federal financial assistance from HHS, not from other Federal agencies, which is consistent with both the 2016 and 2020 Final Rules.

Machine Translation

HHS proposes to define "machine translation" as automated translations, without the assistance of or review by a qualified human translator, that are text-based and provide instant translations

[3] HHS clarifies that these requirements extend to the entire entity, not just the parts that are receiving federal funds.

between various languages, sometimes with an option for audio input or output. **HHS seeks comment on whether this definition is adequate.**

Remedial Action and Voluntary Action

HHS proposes to include requirements for remedial and voluntary action, which was removed in the 2020 Final Rule. This clarifies that Section 1557 also requires covered entities that have engaged in discriminatory conduct with respect to their health programs and activities in violation of this rule to take voluntary actions to remediate the effects of such conduct.

Designation and Responsibilities of a Section 1557 Coordinator

The Proposed Rule reinstates a provision repealed by the 2020 Final Rule requiring covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator. HHS recognizes that some entities may have retained a Section 1557 Coordinator even though the 2020 Final Rule removed the requirement, or that some entities may already have an employee that handles Title IX regulations or Section 504 requirements. Entities may also have multiple employees handling Section 1557 compliance, but the Section 1557 Coordinator is responsible for ultimate oversight of the entity's compliance.

HHS proposes the following responsibilities of the Section 1557 Coordinator:

- Receiving, reviewing, and processing grievances filed under the grievance procedure;
- Coordinating record-keeping requirements;
- Coordinating effective implementation of the language access procedures;
- Coordinating effective implementation of effective communication procedures;
- Coordinating the Covered Entity's procedures for providing reasonable modifications for individuals with disabilities; and
- Coordinating training of relevant employees and maintaining related documentation.

HHS seeks comment on these requirements, specifically whether covered entities with fewer than 15 employees should also be required to have a Section 1557 Coordinator.

Policies, Procedures, and Training

The Proposed Rule requires covered entities to have written nondiscrimination policies and procedures in its covered health programs and activities that consider several bases (i.e., race, color, national origin, sex, age or disability). Generally, covered entities would need to adopt and implement a nondiscrimination policy, grievance procedures, language access procedures and procedures for auxiliary aids and services for the above-mentioned protected classes, and procedures for reasonable modifications for individuals with disabilities. HHS anticipates that consistent procedural requirements across nondiscrimination bases better addresses circumstances where discrimination complaints are alleged on multiple bases. HHS also indicates it will provide sample documents on the agency website.

Written procedures would be designed to reflect the size, complexity, and type of health programs and activities, but must include certain required information. HHS believes most entities will only need to review and update their current policies and procedures as many facilities have already voluntarily created written policies and procedures, but all facilities will need to review their policies to ensure they comply with the Proposed Rule's new requirements. HHS estimates that all covered entities would need to revise at least some of their policies to comply with the new requirements, with about half needing extensive revisions and half needing fewer revisions. HHS estimates the approximate cost for the entities that require extensive revisions is $37.9 million, while the estimated cost for those

entities that require fewer revisions is $22.2 million. HHS estimates that printing the new discrimination notices could range in cost from $47.8 million to $437.2 million.[4] **HHS seeks comment on these policies and procedures.**

HHS also proposes to require covered entities to retain records of grievances for three years to help OCR assess whether there is a pattern of discriminatory behavior. **HHS seeks comment on this proposal as well as input on best practices for record retention and procedures for protecting patient confidentiality.** HHS estimates the cost of retaining records would be about $14.3 million annually.[5]

The Proposed Rule also requires covered entities to train employees on Section 1557 policies and procedures and to document this training. This training will only be required for relevant employees, including those who directly encounter or interact with patients. This training must occur no later than one year after the effective date of the Final Rule. Entities would need to train new employees within a reasonable period of time after the employee joins the workforce. **HHS seeks comment on this proposal, including input from organizations that already have a civil rights training program in place.** HHS estimates this additional training requirement would cost approximately $774.5 million in the first year, and $258 million in years two through five of the implementation period.[6]

Notice of Nondiscrimination

The Proposed Rule requires a recipient of federal financial assistance to provide a notice of nondiscrimination in its health programs and activities to participants, beneficiaries, applicants, and the public. The Proposed Rule lists content requirements for the notice, including that "the covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency (LEP) and primary language), age, or disability in its health programs and activities." The notice must also reference the accommodations for individuals with a disability, including auxiliary aids and services (such as qualified interpreters), and that language assistance services are provided free of charge. The notice must be issued annually and posted in prominent physical locations and on the entity's website, if the entity has one. **HHS seeks comment on whether these provisions are likely to be effective and whether they adequately address the concerns raised in the 2016 and 2020 rules, including whether the content of the notice is sufficient and whether the requirements on where and when the entity must share the notice are sufficient. Additionally, HHS seeks comments on the best ways to provide an accessible initial notice to individuals who may require auxiliary aids and services for their disabilities and the best way in which to provide the notice in a manner accessible to LEP persons. HHS also seeks information from entities that are following the 2016 rule on the costs and burdens of complying with the proposal.**

Notice of the Availability of Language Assistance Services and Auxiliary Aids and Services

HHS proposes to reintroduce the tagline provisions outlined in the 2016 Final Rule, which were removed by the 2020 Final Rule. These provisions require an entity to provide a "notice of availability" stating that the entity provides language assistance services and auxiliary aids and

[4] See Proposed Rule, p. 47900-47904.
[5] HHS does not account for any entities already retaining compliant information in this estimate.
[6] This estimate does not distinguish between the various types of covered entities. The analysis can be found on pp. 47900-4904 of the Proposed Rule.

services free of charge in its health programs and activities. The notice can be provided in a written translation or in recorded audio or video clips. The notice must be provided in English and the 15 most common languages spoken by LEP individuals of the relevant state. The notice must be provided in alternative formats to individuals with disabilities to facilitate effective communication if an individual requests it.

Notice can be provided through written translations or in-language recorded audio or video clips. The notice must be provided annually and on request and be posted conspicuously on the entity's website and in prominent physical locations. Individuals may opt out of the annual notice. The costs associated with complying with all the notice requirements are estimated to be $39.2 million in the first year and about the same cost annually after initial implementation. **HHS seeks comments on whether this proposal is practical and responsive to the concerns raised regarding the 2016 and 2020 Final Rules, specifically those raised regarding burdens associated with the 2016 Final Rule requirements, whether entities should be required to provide the notice in sign language, and the anticipated costs associated with compliance.**

Data Collection

HHS is soliciting feedback and comments on potential data measures OCR can use to collect data beyond those required by the referenced statute and regulations. This data will inform both the Final Rule and OCR's overall civil rights work. Specifically, HHS seeks comments on whether entities are already collecting disaggregated demographic data, such as race, ethnicity, sex, gender, gender identity, sexual orientation, or others, in their health programs and if so, for which categories of data, through what systems, and at what cost. **Further, HHS seeks comments on the types of entities that should be required to submit data and what recipients should be covered.**

Updated Language and Protections Against Sex Discrimination

HHS proposes to update the definition of discrimination "on the basis of sex" to ensure the rule is consistent with case law developed after 2016. Under Section 1557, HHS proposes that prohibited forms of discrimination "on the basis of sex" will include sex stereotypes, characteristics (including intersex traits), pregnancy, sexual orientation, and gender identity. HHS also proposes a prohibition on discriminating on the basis of sex with regards to an individual's marital, parental, or family status. **HHS seeks comment on whether the rule should include protections against discrimination on the basis of pregnancy-related conditions as a form of sex discrimination.**

Meaningful Access for LEP Individuals and Machine Translation

HHS proposes a revision to its prohibition on discrimination on the basis of national origin as applied to LEP individuals by requiring meaningful access for "each limited English proficient individual eligible to be served or likely to be directly affected by its health program and activities." This is not a mandate that every LEP individual receive language services, but instead requires covered entities to take reasonable steps to provide meaningful access to each LEP individual. HHS proposes that when machine translation is used in the healthcare setting, the translation text must be reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an LEP individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language. HHS seeks comment on this proposal.

To assess compliance, HHS proposes that the Director of OCR shall evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the LEP individual. The Director will also take into account certain other

factors, such as the effectiveness of the covered entity's written language access procedures for its health programs and activities that the covered entity has implemented.

HHS also proposes standards for video remote interpreting (VRI) and audio remote interpreting. The standards for VRI were implemented in the 2016 Final Rule, removed in the 2020 Final Rule, and now, HHS proposes to reincorporate these standards. The standards for audio remote interpreting were not included in the 2016 rule, but were introduced in the 2020 Final Rule. This proposal incorporates the same audio remote interpreting standards identified in the 2020 Final Rule.

Discrimination Against Persons with Disabilities

The Proposed Rule requires effective communications for individuals and companions with disabilities. Covered entities would be required to provide auxiliary aids and services to those that require them regardless of the number of people the entity employs. The Proposed Rule also maintains the current accessibility requirements for buildings and facilities. This policy is consistent with the prior rules.

Nondiscrimination in the Use of Clinical Algorithms

The Proposed Rule explicitly states that discrimination based on the use of clinical algorithms[7] is prohibited under Section 1557. HHS acknowledges the prevalence of clinical algorithms as well as the value they provide to the healthcare system. HHS also acknowledges that most entities and providers do not create the algorithms that they use in daily practice. However, HHS cautions against an overreliance on clinical algorithms, and states that they should never be used as a substitute for a practitioner's clinical judgment. Further, HHS proposes a policy that if discrimination occurred because of the use of a clinical algorithm, the provider may be liable even if they did not create the algorithm. If OCR receives a complaint alleging discrimination resulting from the use of a clinical algorithm in decision-making against a covered entity, OCR will conduct a fact-specific analysis of the allegation, considering, among other things, what decisions and actions were taken by the entity in reliance upon a clinical algorithm and what measures the entity took to ensure that its decisions and actions resulting from using a clinical algorithm were not discriminatory. **HHS seeks comment on the inclusion of this proposal, whether the policy should be expanded to other types of technology, what practices could be used to ensure entities are complying with this section, and what possible defenses a covered entity might have when using a clinical algorithm in decision-making that results in discrimination.**

Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services

Neither the 2016 nor the 2020 Final Rule included a section on telehealth. However, with the acceleration in utilization of telehealth driven by the COVID-19 pandemic, HHS proposes to include a section addressing nondiscrimination in telehealth services. This proposal would prohibit a covered entity from discriminating on the basis of race, color, national origin, sex, age, or disability in the provision of telehealth services for its programs and activities. HHS acknowledges that telehealth provides important benefits for patients, but that telehealth is also subject to accessibility challenges for some groups. Covered entities that provide telehealth services must do so in a nondiscriminatory manner on a protected basis and must provide effective communication, including

[7] Clinical algorithms are tools used to guide health care decision-making and can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models.

language assistance services for LEP individuals and auxiliary aids and services. This also includes remote patient monitoring devices, which may be challenging for patients with limited dexterity. **HHS seeks comment on this approach.**

Enforcement

The Proposed Rule incorporates the existing enforcement mechanisms provided for under other civil rights statutes, including Title VI, Title IX, Section 794, and the Age Discrimination Act. HHS states that Section 1557 creates a private right of action based on recent Supreme Court precedent, allowing individuals to sue a covered entity in a federal court.

HHS also proposes specific procedures for administrative enforcement. For recipients and state exchanges, Title VI procedures would be used for enforcement actions based on race, color, national origin, sex, and disability. Age Act procedures would apply for age discrimination complaints. HHS would also adopt procedures for when a recipient fails to respond to OCR in a timely fashion.

HHS proposes to adopt the procedures for complaints enumerated in Section 504 to any claims of discrimination made under Section 1557 against HHS or the programs and activities it administers, including the Federally-facilitated exchanges. This proposal requires HHS to provide OCR with access to information relevant to compliance with Section 1557 and prevents HHS from retaliating against the complainant. This proposal is consistent with a policy included in the 2016 Final Rule that was removed in the 2020 Final Rule.

Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws

HHS proposes a new process for recipients who believe that compliance with Section 1557 policies would violate Federal conscience or religious freedom laws. The entity may notify HHS that compliance with a provision of Section 1557 as applied would violate Federal conscience or religious freedom laws. HHS will consider the entity's views in responding to complaints or proceeding with any investigation of enforcement activity. OCR will have discretion in determining whether a recipient is exempt from or entitled to a modification based on a sufficiently concrete factual basis and applicable legal standard.

CMS Amendments

The 2020 Final Rule amended provisions in CMS regulations that removed the language prohibiting discrimination on the basis of sexual orientation and gender identity. The Proposed Rule aims to identify prohibited discrimination on the basis of sexual orientation and gender identity in certain CMS programs by reinstating the ten CMS regulations that were deleted by the 2020 Final Rule. In addition to restoring these provisions, CMS has also proposed to apply these protections to the Medicaid fee-for-service programs and managed care delivery systems.

What's Next?

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. This feedback will help inform our comments to the agency. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Emily Jones, Regulatory Affairs and Administration Policy Director in the Washington, D.C. office.