

Third Times the Charm: The Biden administration's Final Rule for Sec. 1557

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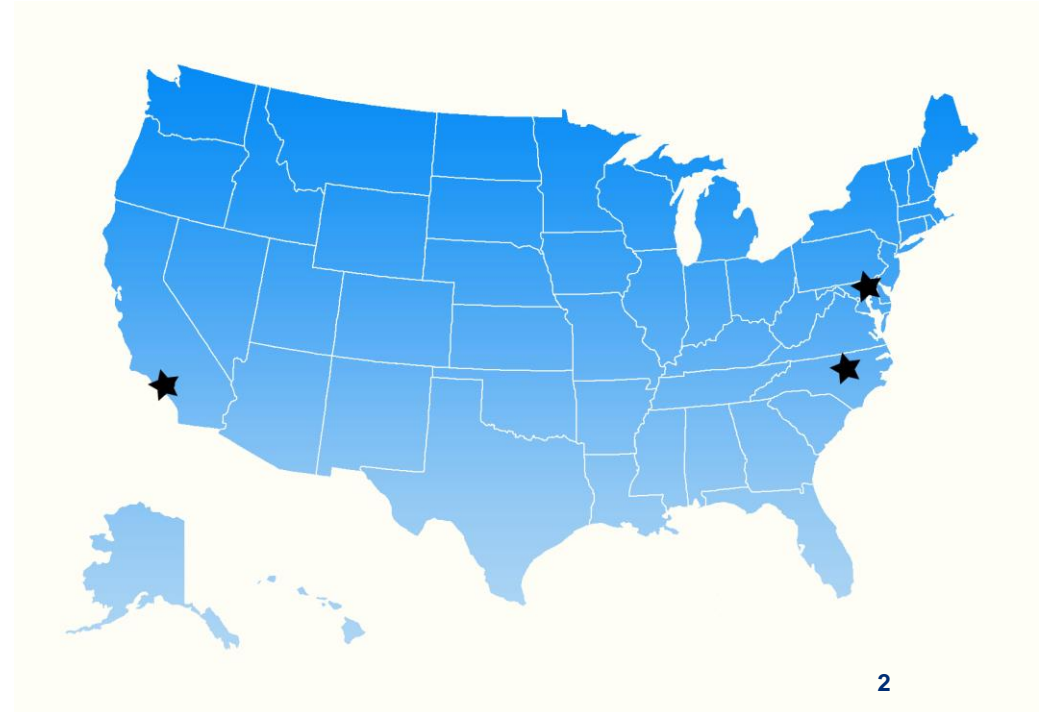
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CCHI Webinar, May 22, 2024



About NHeLP

- National non-profit law firm committed to improving health care access and quality for underserved individuals and families
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Roadmap

- Background
- Final Regulations
 - Definitions
 - General Requirements
 - Language Access Requirements
- Filing Section 1557 Complaints
- Next Steps
- Questions

May 6, 2024

- HHS Office for Civil Rights (OCR) issued [final regulations](#) implementing Section 1557 of the Affordable Care Act
- This is the **THIRD** set of regulations implementing Section 1557
 - The new final regulations propose to repeal many of the [Trump-era](#) provisions, update/amend some [Obama-era](#) provisions, and add some new provisions

Background

BACKGROUND:

Title VI of the Civil Rights Act of 1964

- Title VI is where the right to language access started
 - “No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 42 U.S.C. § 2000d
 - “National origin” includes individuals with limited English proficiency (LEP)
- Title VI, its implementing regulations and the OCR LEP Guidance (based on Title VI) all remain in effect

BACKGROUND:

Section 1557 of the ACA

- Broad nondiscrimination protection
- Reinforces longstanding protections for race, ethnicity, **national origin**, age & disability
- First time healthcare discrimination is prohibited based on sex including:
 - sexual orientation
 - gender identity, including transgender individuals
 - sex stereotyping
 - sexual characteristics including Intersex traits
- Final rule also recognizes intersectionality – “or any combination thereof”

BACKGROUND:

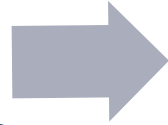
Goal of Section 1557

- Bring all civil rights protections under 1 provision
 - Title VI (discrimination on the basis of race/color/national origin)
 - Title IX (discrimination on the basis of sex)
 - Sec. 504 (discrimination on the basis of disability)
 - Age Discrimination
- Why?
 - Intersectionality
 - Differing remedies under each civil rights law
 - Expand protections against sex discrimination into health care

Hierarchy of Law

Statute

- Passed by Congress & signed by President
- Can't be changed without enacting a new law



Regulations

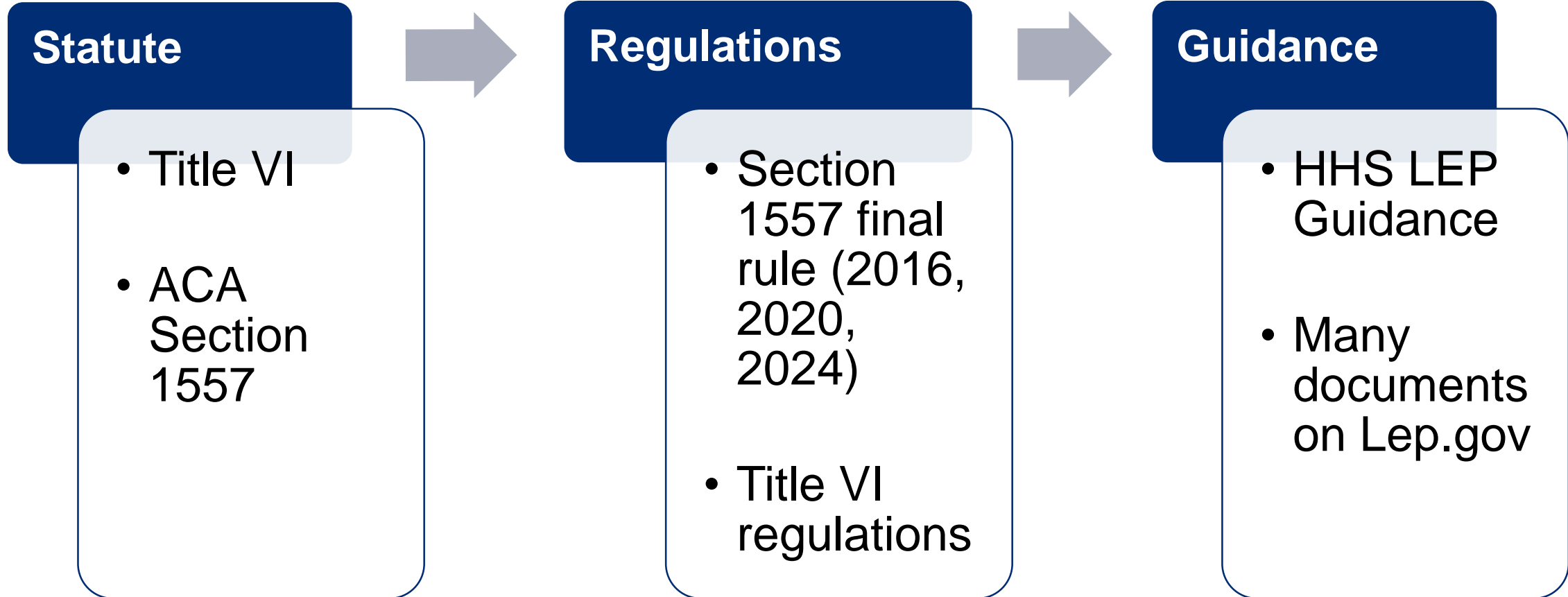
- Developed by Agencies
- Requires Public Comment process
- Can't be changed without new public comment process



Guidance

- Developed by Agencies
- Usually no public comment process
- Can be changed by agency
- Includes Executive Orders, FAQ

Hierarchy of Law



BACKGROUND:

Section 1557 – Scope

- any health program or activity **any part of which** receives federal funding;
- any health program or activity that is administered by an Executive agency; and
- any entity created under Title I of the Affordable Care Act (including health insurance marketplaces)

- This is **broader** than Title VI which only applied to those receiving federal funding

- Section 1557 only applies to health programs/activities but Title VI applies to **all** federal funding

BACKGROUND: Who Is Covered?

Title VI & Sec. 1557

- All public and private entities receiving federal financial assistance, including:
 - State, county, and local agencies (inc. Medicaid, CHIP)
 - Hospitals, clinics, and clinicians' offices
 - Refugee resettlement agencies
 - Nursing homes
 - Mental Health Centers
 - All entities receiving federal funds or under contract to those receiving federal funds

Section 1557

- Federally administered programs
 - Medicare
 - Federally Facilitated Marketplace
- Entities created under ACA Title I
 - state marketplaces
 - Qualified Health Plans (also receive federal funds)

New Final Regulations

New Final Regulations (May 6, 2024)

- Changes 2020 final regulations implementing Section 1557
- Significant changes outside of language access:
 - Reinstates protections against discrimination based on gender identity, sex stereotypes and pregnancy & related conditions; adds protections against discrimination based on sexual orientation & sex characteristics inc. intersex traits
 - Reinstates definition section
 - Reinstates requirements to have a Section 1557 compliance coordinator and written grievance procedures and requires staff training
 - Reinstates enforcement-related provisions & remedies
 - Reinstates other regulations in Medicaid, Medicare, CHIP & Marketplaces to provide explicit nondiscrimination protections based on sexual orientation and gender identity

Final Regulations: Definitions

Definitions: General

- Includes:
 - covered entity
 - federal financial assistance
 - health program or activity
 - recipient
 - telehealth

Definitions: Language Access

- Defines national origin, individual with limited English proficiency, language assistance services, relay interpretation, companion
- **Language assistance services** may include, but are not limited to:
 - oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for a limited English proficient individual, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;
 - written translation, performed by a qualified translator, of written content in paper or electronic form into or from languages other than English; and
 - written notice of availability of language assistance services

Definition: Qualified Interpreter/Translator for an individual with limited English proficiency

- Reinstates & tweaks definition; interpreter/translator is an individual who:
 - has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language (or 2 non-English languages for relay interpreter)
 - is able to interpret/translate effectively, accurately, and impartially, both receptively and expressively , using any necessary specialized vocabulary while preserving the tone, sentiment, and emotional level of the original oral statement
 - adheres to generally accepted interpreter ethics principles including client confidentiality
- Includes recognition of relay interpreters
- **NOTE**: Due to this definition, implicit recognition that not all interpreters can translate and vice versa

Definition: Qualified Interpreter/Translator for an individual with a disability

- Aligns more closely with definition of qualified interpreter for LEP individual:
 - has demonstrated proficiency in communicating in, and understanding:
 - both English and a non-English language (including American Sign Language, other sign languages); or
 - another communication modality (such as cued-language transliterators or oral transliteration);
 - is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original statement; and
 - adheres to generally accepted interpreter ethics principles including client confidentiality.
- Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators

Definition: Auxiliary Aids and Services

- Qualified interpreters (on-site and VRI)
- Note takers; real-time computer-aided transcription services; written materials; exchange of written notes
- Telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning
- Voice, text, and video-based telecommunications products and systems; videotext displays; accessible information and communication technology (ICT); or other effective methods of making aurally delivered information available to persons who are deaf or hard of hearing
- Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to persons who are blind or have low vision
- Acquisition or modification of equipment and devices
- Other similar services and actions
- This is **not** an exhaustive list

Definition: Qualified bilingual/multilingual staff

- An individual who is a member of a covered entity's workforce who is designated to provide in-language oral assistance as part of the person's current assigned job responsibilities who has demonstrated to the covered entity that they are:
 - proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and
 - able to effectively, accurately, and impartially communicate directly with limited English proficient individuals in their primary languages

Definition: Machine Translation

- automated translation, without the assistance of or review by a qualified human translator, that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output
- a qualified human translator must review machine translation if an entity uses machine translation for text that is critical to the:
 - rights, benefits, or meaningful access of a limited English proficient individual;
 - when accuracy is essential; or
 - when the source documents or materials contain complex, non-literal or technical language

Final Regulations: General Requirements

Application

- § 1557 applies to “any health program or activity, any part of which is receiving Federal financial assistance”
- Providing or administering health insurance is a health program/activity and if there is federal financial assistance, it applies to:
 - third party administrators
 - short-term limited duration insurance plans
 - limited benefit plans
 - pharmacy benefit managers

General Requirements

- Develop specific policies & procedures
- Disseminate Notice of Nondiscrimination & Notice of Availability of Language Assistance Services and Auxiliary Aids and Services
- Designate Sec. 1557 coordinator (entities with 15 or more employees)
- Develop grievance procedures (entities with 15 or more employees)
- Train relevant staff

Policies & Procedures

- Covered entities must develop written policies & procedures to comply with the regulations
- Policies must include:
 - Nondiscrimination policy
 - Grievance procedures (15 or more employees)
 - Language access procedures
 - Effective communication procedures for persons with disabilities
 - Reasonable modification procedures

Notice of Nondiscrimination

- Entities must notify individuals and the public of all of the following:
 - nondiscrimination policy
 - reasonable modifications for individuals with disabilities and appropriate auxiliary aids & services, qualified interpreters and materials in alternate formats free of charge and in a timely manner
 - language assistance services including electronic and written translated documents and oral interpretation free of charge and in a timely manner
 - how to obtain reasonable modifications, appropriate auxiliary aids & services, and language assistance services
 - contact information for the entity's Section 1557 coordinator
 - availability of the grievance procedures and how to file a grievance
 - details on how to file a complaint with HHS OCR
 - how to access the covered entity's website (if it has one)
- Notice must be provided annually, upon request, and in a clear and prominent physical locations

Notice of availability of language assistance services and auxiliary aids and services

- Notice must be provided in English and at least the top 15 languages in the state:
 - annually
 - upon request
 - at a conspicuous location on the entity's website
 - in a clear and prominent physical location in no smaller than 20-point sans serif font
 - in alternate formats for individuals with disabilities who require auxiliary aids & services
- Opt out option available
- Specific tagline requirements also exist in other federal regulations
 - e.g. Medicare Part D (Rx program)

Notice of availability of language assistance services and auxiliary aids and services

- Notice must appear in certain written & electronic communications (this changes prior tagline requirement for “significant” documents):

notice of nondiscrimination

consent forms and certain instructions

notice of privacy practices

complaint forms

application and intake forms

patient and member handbook

notices of denial or termination of eligibility, benefits or services (including Explanation of Benefits) and notices of appeal and grievance rights

communications related to a person’s rights, eligibility, benefits or services that require or request a response

communication related to cost/payment of care including medical billing/collection materials & good faith estimates

communication related to a public health emergency

discharge papers

Policies & Procedures: Language Access

- Language access procedures must include:
 - current contact information for the Section 1557 coordinator;
 - how an employee identifies whether an individual has limited English proficiency;
 - how the employee obtains the services of qualified interpreters and translators the entity uses
 - the names of any qualified bilingual staff members; and
 - a list of any electronic and written translated materials the entity has, the languages they are translated into, date of issuance, and how to access electronic translations
- Similar requirements for effective communication procedures for persons with disabilities with addition of how to access appropriate auxiliary aids & services

Section 1557 Coordinator

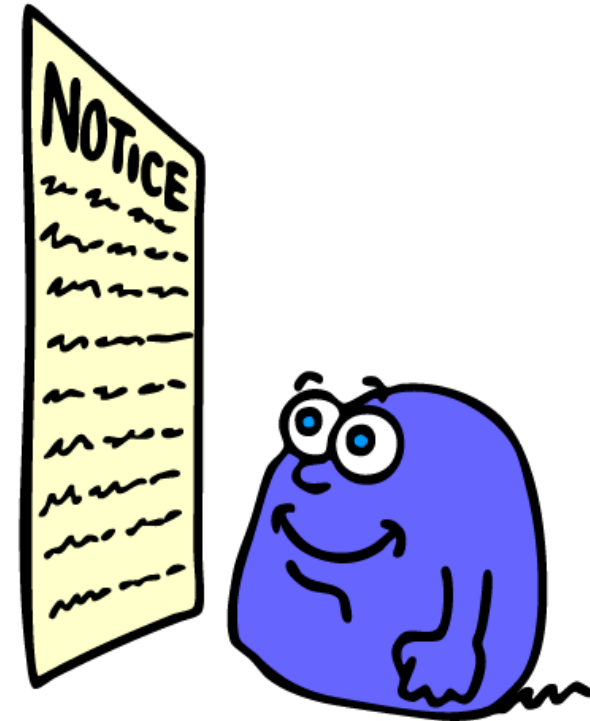
- Designate and authorize at least one **employee** as a Section 1557 Coordinator to coordinate compliance with its responsibilities under Section 1557
- Responsibilities:
 - receives, reviews & processes grievances
 - coordinates recordkeeping requirements
 - coordinates effective implementation of language access & effective communication procedures
 - coordinates effective implementation of reasonable modification procedure
 - coordinates training of relevant employees
- Applicable to entities with 15 or more employees

Train Staff

- Entities must train “**relevant employees**” on the civil rights policies & procedures outlined in the proposed rule & document training
- Training must be provided within as soon as possible but no later than 30 days following implementation of the required policies & procedures (and no later than May 1, 2025)
- “Relevant employee” – permanent and temporary employees
 - those who directly encounter or interact with individuals such as patients, clients, and members of the public;
 - those who make decisions regarding the services individuals seek from a covered entity’s health programs and activities including executive leadership team and legal counsel; and
 - those who perform tasks and make decisions that directly or indirectly affect patients’ financial obligations including billing and collections

Adoption of Grievance Procedures

- Must have written grievance procedure that provide for prompt & equitable resolution
- Must retain records related to grievances filed for no less than 3 calendar years
- Must keep confidential the identity of an individual who file a grievance except as required by law or to the extent necessary to carry out the purposes of these regulations including the conduct of any investigation



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Final Regulations: Language Access Requirements

LEP General Requirement

- Focus is on the **individual** eligible to be served or likely to be directly affected
- A covered entity must take reasonable steps to provide meaningful access to each limited English proficient individual
- In evaluating compliance with ensuring meaningful access, OCR shall:
 - evaluate and give substantial weight to the nature and importance of the health program/activity and the particular communication at issue; and
 - take into account other relevant factors, including the effectiveness of a covered entity's written language access procedures

Language assistance services requirements

- Free of charge
- Accurate
- Timely
- Protect the privacy & independent decision-making authority of the LEP individual
- Cannot rely on staff other than qualified interpreters, qualified translators, or qualified bilingual/multilingual staff to communicate with individuals with limited English proficiency

Use of Family Members/Minors

- Prohibits use of accompany adults & minors except **as a temporary measure** in emergencies
- Prohibits reliance on staff other than qualified bilingual/multilingual staff to communicate with individuals with LEP
- Individual can use an accompanying adult as an interpreter if that person:
 - agrees to do so;
 - the request & agreement is documented; and
 - reliance on that adult is **appropriate under the circumstances**



NOTE: Some entities may want to have their own interpreter present even if a patient wants to use a family member/friend

Translation of Written Materials

- No specific requirements or thresholds for when to translate documents in statutes or regulations
- HHS LEP Guidance (2003) recommended translating “vital” documents & includes safe harbor

SUMMARY

“Vital” documents should be translated
“Notice of availability” must be included in certain communications



Artificial Intelligence

- Specific provision prohibits discrimination in the use of “patient care decision support tools”
- Automated or non-automated tool used to “support clinical decision-making”
 - Clinical care and diagnosis
 - Prior authorization and level of care
 - Crisis standards of care
- Duty to identify and mitigate risk of discrimination
- Sec. 1557 also applies to other uses of AI in healthcare

Medicare Part B

- Historically, Title VI has **not** applied to Medicare Part B (outpatient coverage)
 - In part because Medicare Part B paid enrollees and not providers
- The final rule **finally** applies Section 1557 to Medicare Part B
 - Also applies T. VI & T. IX and Sec. 504, & Age Act to Medicare Part B
- This is a significant development
 - the way Medicare pays Part B providers is now no different than how it pays other Medicare, Medicaid or CHIP providers

Other Relevant Provisions

- Telehealth
- Basis of Association
- Prohibition of sex discrimination in other HHS programs inc. Medicaid, CHIP, PACE, marketplaces

Filing Section 1557 Complaints

Enforcement mechanisms

- 2024 Final Rule creates administrative procedures for
 - Recipients of Federal Financial Assistance and State Based Marketplaces § 92.303 (Title VI)
 - Federal health programs and agencies § 92.304 (Sec. 504)
- Resolution agreements posted to HHS OCR website
- Complaint driven but HHS OCR may conduct compliance review
- HHS will coordinate with other agencies
 - Other agencies do not yet have Sec. 1557 regulations
 - Sometimes jurisdiction is with another agency – e.g. employment issues go to EEOC

Filing with OCR

- If you or someone you know experiences health care discrimination on the basis of race, color (ethnicity), national origin (limited English proficiency), disability, age, sex (pregnancy or related conditions including abortion, sex stereotypes, gender identity, sex characteristics including intersex traits), you can file a complaint directly with HHS OCR by mail, e-mail, fax, or the OCR complaint portal.
- Must file within 180 days of when you knew the act or omission (e.g., denial of care) occurred.
- <https://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html>

Next Steps

So where are we?

- Title VI is still law!
- Section 1557 is still law!
- HHS OCR LEP Guidance (2003) still in effect!
- The proposed regulations are **not** in effect yet but will be VERY shortly!

Effective Dates

- March 23, 2010 – Section 1557 effective
- July 5, 2024 – most of the 2024 Final Rule becomes effective
- 1st day of first plan year after Jan 1, 2025 – for entities **newly** covered:
 - provisions requiring changes in health insurance or other health-related coverage
 - benefit design discrimination

Other Effective Dates

Regulatory Provision	Compliance Date
Section 1557 Coordinator Notice of Nondiscrimination	By November 2, 2024
Policies and Procedures “Notice of Availability”	By July 5, 2025
Training	Following implementation of the policies & procedures; no later than May 1, 2025
Patient care decision support tools	By May 1, 2025

State Laws

- Check for state nondiscrimination laws & regulations
- Check for state language access laws & regulations
 - [Summary of State Law Requirements Addressing Language Needs in Health Care](#) (2019 update)

NHeLP Resources

- NHeLP's [website](#)
- [Section 1557 webpage](#)
- [Section 1557 Final Rule analysis](#)
- [Issue Brief on Title VI and Section 1557](#)
- [Medicaid and CHIP Reimbursement Models for Language Services: 2024 Update](#)
- [The High Costs of Language Barriers in Medical Malpractice](#)

Your questions



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