# THE 2024 SECTION 1557 FINAL RULE:

# PRESENTATION TO THE MEDICAL SOCIETY OF NEW JERSEY

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### SECTION 1557 OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

42 U.S.C. § 18116(a)

"Section 1557 prohibits discrimination on the basis of race, color, national origin, age, disability, or sex (including pregnancy, sexual orientation, and gender identity), in covered health programs or activities."

### ...But what does that mean?

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# WHAT IS SECTION 1557 OF THE AFFORDABLE CARE ACT?

# The nation's first health care-specific civil rights law.

- The nation's first federal civil rights law to:
  - focus exclusively on nondiscrimination in health care; and
  - to prohibit discrimination on the basis of sex in health care.
- Prohibits covered entities that administer health programs and activities from excluding from participation, denying program benefits, or discriminating based on certain characteristics.

#### Incorporates four major civil rights laws:

- Title VI of the Civil Rights Act;
  - Race
  - Color
  - National Origin (including in language)
- Title IX of the Education Amendments of 1972;
  - Sex
- Section 504 of the Rehabilitation Act of 1973; and
  - Disability
- Age Discrimination Act of 1975.
  - Age

### SECTION 1557 OF THE AFFORDABLE CARE ACT

### **Objectives of Section 1557**

Expand access to health care and coverage

Eliminate barriers Reduce health disparities

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### SECTION 1557 OF THE AFFORDABLE CARE ACT

### **Objectives of Section 1557**

CONTINUED

Apply nondiscrimination protections to telehealth and patient care decision support tools, including artificial intelligence and machine learning Recognize protections against discrimination on the basis of sex, including sexual orientation and gender identity, consistent with the holding in *Bostock v. Clayton County* 

# SECTION 1557 APPLIES TO ALL COVERED ENTITIES

- Covered entities are health programs and activities that receive Federal financial assistance from the U.S. Department of Health and Human Services (HHS). With the 2024 Final Rule, this includes recipients of Part B funds.
- Covered entities must provide equal access to health care, health insurance coverage, and other health programs without discrimination based on protected characteristics.
- For example, hospitals, health clinics, physician's practices, community health centers, nursing homes, rehabilitation centers, health insurance issuers, and state Medicaid agencies are all covered entities.
- Federal financial assistance includes the receipt of grants, property, Medicaid, Medicare (Parts A, C, and D), and/or taking credits and cost-sharing subsidies under Title I of the Affordable Care Act (ACA).
- All entities that principally engage in health services or health coverage:
  - When an entity principally engages in health services or health coverage, all of the entity's operations are considered part of the health program or activity and must comply with Section 1557.
  - This includes, for example, each of a hospital's medical departments, as well as its cafeteria and gift shop.

# HISTORY OF SECTION 1557 OF THE AFFORDABLE CARE ACT

- The U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) received and acknowledged nearly 25,000 comments on the proposal of Section 1557.
- The Obama administration issued the first final rule for Section 1557 in 2016:
  - Required covered entities to provide equal access to health programs and activities without discrimination based on:
    - Sex (including pregnancy, false pregnancy, termination of pregnancy, recovery from childbirth, or related conditions);
    - Sex stereotypes; and
    - Gender identity (including gender expression and transgender status).
  - Did not resolve whether the statute prohibited discrimination based on "sexual orientation status" alone;
  - Did not include a blanket religious exemption related to the statute's general prohibition against sex discrimination; and

7

Interprets the statute to allow a private right of action and compensatory damages.

# HISTORY OF SECTION 1557 OF THE AFFORDABLE CARE ACT

- The Trump administration reconsidered the regulation and reversed several of the original provisions in its 2020 final rule:
  - Eliminated the general prohibition on discrimination based on gender identity and sex stereotyping, reverting to the "plain meaning of the term sex" to refer to binary male and female individuals;
  - Did not recognize discrimination based on "sexual orientation status" alone;
  - Adopted blanket abortion and religious freedom exemptions for health care providers; and
  - Eliminated provisions affirming a private right of action so that individuals could challenge alleged violations of Section 1557 and obtain money damages (leaving the right to sue for the courts to decide).
- As of 2021, the Biden administration interprets and enforces Section 1557's prohibitions on discrimination based on sex to include discrimination based on sexual orientation and/or gender identity.

# KEY REQUIREMENTS OF THE 2024 FINAL RULE

- The most significant change in the 2024 final rule (when compared to the prior versions) is in the expanded definition of "sex" as a protected characteristic.
  - Prohibits covered entities from imposing restrictions on the care provided based on a patient's gender identity or sex assigned at birth.
- Inclusion of Part B recipients as covered entities.
- Requires that practices take a number of affirmative actions to inform patients of their rights and protect them from discrimination.
- Expanded assistance for individuals with limited English proficiency (LEP) and disabilities.
- Requires providers to make reasonable efforts to mitigate discrimination in patient support tools.

### SECTION 1557 ENFORCEMENT BY HHS' OFFICE OF CIVIL RIGHTS: CONSEQUENCES OF NONCOMPLIANCE

- HHS OCR enforces Section 1557 as to programs that receive funding from HHS.
- OCR is a neutral, fact-finding agency that receives, investigates, and resolves thousands of complaints from the public alleging discrimination in health services and health coverage.
- When OCR finds a violation of Section 1557, OCR will seek the voluntary cooperation of the covered entity to take corrective action, which may include:
  - Revising policies and procedures; and/or
  - Implementing training and monitoring programs.
- If a covered entity refuses to take corrective actions, OCR may:
  - Recommend the suspension or termination of the violator's federal financial assistance; or
  - Refer the matter to the U.S. Department of Justice for possible enforcement proceedings.
- The rule does not specifically address fines or penalties from HHS, but there is private right of action under Section 1557.

### PROVISIONS OF THE 2024 SECTION 1557 FINAL RULE: REQUIREMENTS FOR FACILITIES WITH 15 OR MORE EMPLOYEES

Section 1557 requirement	Timeline by which covered entities must comply	Date by which covered entities must comply
Designate a Section 1557 coordinator who will be responsible for carrying out the covered entity's organizational requirements.	Within 120 days of the effective date.	November 2, 2024.

### PROVISIONS OF THE 2024 SECTION 1557 FINAL RULE: THE SECTION 1557 COORDINATOR

- Employees include full or part-time employees and/or independent contractors.
- Must designate at least one employee as a Section 1557 Coordinator who will be responsible for serving as an internal resource dedicated to coordinating and ensuring the covered entity's compliance with the Rule.
- Significant responsibilities will be to receive, review, and investigate any grievance communicated to the covered entity — be it from a patient, employee, or other source alleging noncompliance with Section 1557.

### PROVISIONS OF THE 2024 SECTION 1557 FINAL RULE: ADDITIONAL REQUIREMENTS FOR FACILITIES WITH 15 OR MORE EMPLOYEES

- Facilities must implement written civil rights grievance procedures for its health programs and activities that provide for the "prompt and equitable resolution" of any allegations that would be prohibited by Section 1557:
  - The grievance procedure must be accessible to individuals with limited English proficiency and individuals with disabilities.
- Retain records related to grievances filed with it that allege discrimination in its health care programs or activities for no less than three years.
- Keep the identity of the individual who filed the grievance confidential unless disclosure is required by law or necessary to its investigation.

### **Policies and Procedures**

Section 1557 requirement	Timeline by which covered entities must comply	Date by which covered entities must comply
Develop and implement written policies and procedures to facilitate compliance with Section 1557.	Within one year of the effective date.	July 5, 2025.

#### **Policies and Procedures**

- Facilities must develop and implement written policies and procedures designed to facilitate compliance with the rule, including:
  - Nondiscrimination policy;
  - Language access procedure;
  - Auxiliary aids and service procedures; and
  - Procedures for reasonable modification for individuals with disabilities.
- Policies and procedures must:
  - Include an effective date;
  - Be reasonably designed; and
  - Take into account the size, complexity, and type of the facility's health programs/activities.

### **Notice of Availability**

Section 1557 Requirement	Timeline by which covered entities must comply	Date by which covered entities must comply
Post and provide a Notice of Availability of Language Assistance Services and Auxiliary Aids and Services in English and in each of the area's 15 most common non-English languages to inform individuals of the availability of language assistance services and auxiliary aids and services free of charge.	Within one year of the effective date.	July 5, 2025.

# PROVISIONS OF THE 2024 SECTION 1557 FINAL RULE: LEP REQUIREMENTS

- Facilities must provide individuals with limited English proficiency "meaningful access" to services.
- Facilities must take "reasonable steps" to provide "meaningful access" to each limited English proficient individual, including their companions, eligible to be served or likely to be directly affected by its health programs/activities.
- Facilities may not:
  - Require an LEP individual to provide their own interpreter or pay the cost;
  - Rely on an adult who is not a qualified interpreter;
  - Rely on a minor child; and
  - Rely on staff other than *qualified* interpreters, translators, or bilingual/multilingual staff.
- The final rule does not specifically state that a provider can or cannot use Google Translate to meet the requirements of the rule.
  - However, one commenter pointed out that Google Translate incorrectly translated information regarding vaccines that was used on a government website.
  - HHS requires that for certain critical documents, any machine translation (i.e., Google Translate) be reviewed by a qualified translator.
  - In addition, HHS recommends that if machine translation is used in circumstances that do not require human review, patients should be warned that it may contain errors.

#### **Notice of Availability**

- Must state that the facility provides language assistance services and appropriate auxiliary aids and services, free of charge, when necessary for compliance to participants, beneficiaries, enrollees, and applicants of its health programs/activities and members of the public.
- Must be posted conspicuously and be provided in a number of electronic and written communications.

### **Notice of Nondiscrimination**

Section 1557 requirement	Timeline by which covered entities must comply	Date by which covered entities must comply
Post and provide a Notice of Nondiscrimination to participants, beneficiaries, enrollees, and applicants of their health programs and activities, and to the public.	Within 120 days of the effective date.	November 2, 2024.

#### **Notice of Nondiscrimination**

- Must be provided to participants, beneficiaries, enrollees, and applicants to a facilities health programs/activities and members of the public.
- Must convey the availability of the services and modifications required by the new policies and procedures.
- Must be posted in conspicuous locations and readily provided.

### **Staff & Employee Training**

Section 1557 requirement	Timeline by which covered entities must comply	Date by which covered entities must comply
Train relevant employees on the covered entity's Section 1557 policies and procedures.	Begin training employees no later than thirty (30) days after the covered entity implements its policies and procedures and no later than three-hundred (300) days after the effective date.	effective date).

#### **Staff & Employee Training**

- Must train relevant employees of the health programs/activities on the new civil rights policies.
- "Relevant employees" is interpreted broadly as permanent and temporary employees whose roles and responsibilities entail:
  - Interacting with residents and members of the public;
  - Make decisions that directly or indirectly affect residents' health care, including the covered entity's executive leadership team and legal counsel; and
  - Performing tasks and making decisions that directly or indirectly affect residents' financial obligations, including billing and collections.
- Training must be provided in a "reasonable amount of time":
  - To new employees; and
  - After any material change in the policies or procedures.

### PROVISIONS OF THE 2024 SECTION 1557 FINAL RULE: NONDISCRIMINATION IN TELEHEALTH

- Joint guidance from HHS and the Department of Justice issued in 2022 already prohibits covered entities from using telehealth in a discriminatory manner.
- HHS believes that additional regulation of telehealth is necessary given the substantial expansion in the use of telehealth technologies and the barriers in access to care that continue to be experienced by some individuals.
  - Particularly important because telehealth services can be inaccessible to individuals with disabilities.

# QUESTIONS RECEIVED PRIOR TO THE PRESENTATION

#### • Did CMS provide a billing code for translation services?

- CMS has an HCPCS code for sign language and oral interpretative services (under Other Services). However, it is unclear how it applies to Section 1557's expanded requirements.
- Where do we find translation services that are affordable?
  - We are unfortunately unable to recommend specific vendors. However, some professional organizations may have suggestions or recommendations.
- Will we need to update our informed consent and intake forms to accommodate the top 15 languages?
  - The rule does not discuss informed consents in this context, but the requirement is that the Notice of Availability be provided in English and the top 15 non-English languages, not "all information."
- How do I know if there is bias in my algorithm or app that I use to help with patient selection for treatments?
  - Identify tools that use input variables or factors that measure race, color, national origin, sex, age, or disability;
  - HHS expects identification of patient care decision support tool that are "known to use indirect measures for race, color, national origin, sex, age or disability, which could result in prohibited discrimination".
  - Is there reason to believe that the tool uses such variables or factors and could result in discrimination? This information can be
    obtained from the developer of the tool, from journals or media reports, from HHS, or from other health care providers.
  - Examples provided by HHS: eGFR equation; tools to assess risk of heart failure; obstetrical tools to assess risks associated with vaginal birth after c-section.

### HHS RESOURCES REGARDING SECTION 1557

- <u>FAQs</u>
- Fact Sheet
- <u>Sample Notices of Non-Discrimination and Notices of Availability in Multiple Languages</u>
- Text of the 2024 Final Rule

# **Q&A DISCUSSION**

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26

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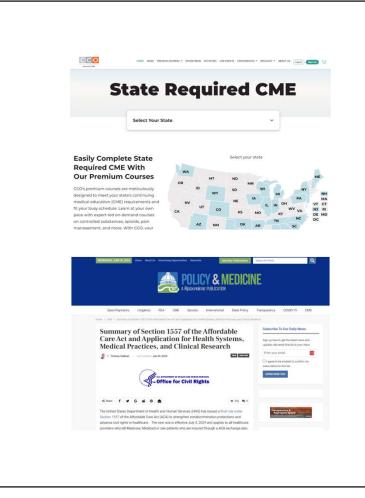
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