What the New Section 1557 Rule Means for Health Insurance Non-Discrimination Protections and Considerations for Regulators

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Presented by:

- Wayne Turner, National Health Law Program
- Carl Schmid, HIV+Hep Policy Institute
- Kellan Baker, Whitman Walker Institute
- Dorianne Mason, National Women's Law Center

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Roadmap

- Section 1557 background, scope and applicability
- Discriminatory benefit design
- Prescription drug access
- Nondiscrimination on the basis of sex
- Health care refusals and exemptions
- Key issues for regulators

Section 1557:
Overview and Regulatory History

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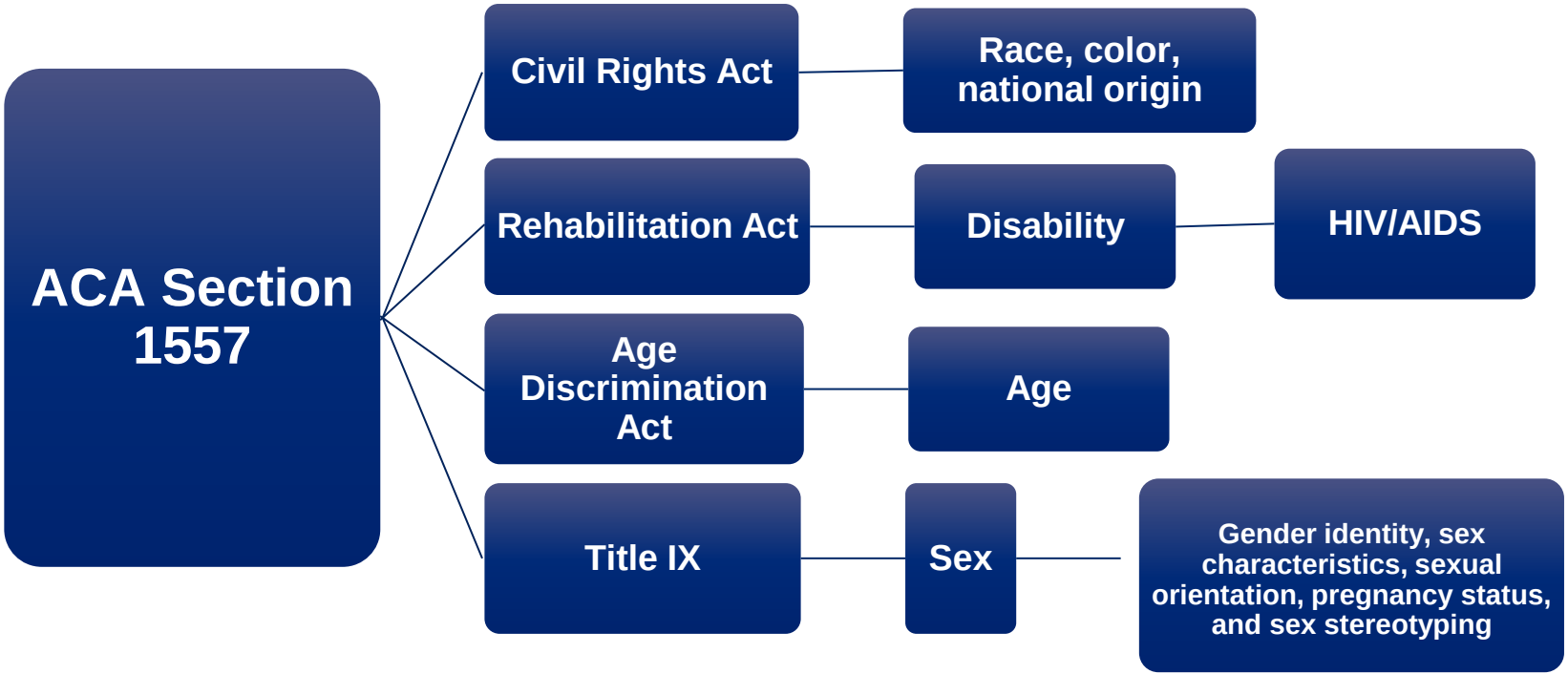
ACA Nondiscrimination Protections

- **Market reforms** (e.g, no preexisting conditions exclusions, no lifetime or annual caps)
- **Essential health benefits** – benefit design must not discriminate based on “present or predicted disability, degree of medical dependency, quality of life, or other health conditions”
- **QHPs** – no marketing or benefit design that “discourages persons with significant health needs from enrolling”
- **Section 1557** – no discrimination in health programs or activities receiving federal financial assistance

Section 1557: Nondiscrimination in Coverage and Care



Section 1557 Timeline

- ACA enacted – March 23, 2010
- Request for Information (RFI) – August 2013
- Notice of Proposed Rulemaking (NPRM) – September 2015
- Final 2016 Rule published – May 2016
- Trump administration NPRM – May 2019
- Final 2020 Rule published – June 2020
- HHS Notice of Interpretation on *Bostock* – May 2021
- NPRM – August-October 2022
- Final Rule expected – Spring 2024

Changes in 2020 Final Rule

- Narrowed applicability by exempting a broad array of federal health care programs and activities
- Declared that an entity “principally engaged in providing health ***insurance*** shall not be considered to be principally engaged in providing health ***care***”
- Removed provisions against discriminatory health plan benefit design
- Eliminated regulatory protections against sex discrimination that included gender identity, sexual orientation, sex stereotyping, and pregnancy status
- Sanctioned discrimination by religiously affiliated hospitals, providers, and health plans
- Limited enforcement by restricting the ability to file court actions

2022 Proposed Changes - Applicability

- Clarifies that §1557 applies to all federal health programs and activities (not just ACA)
- Providing or administering health insurance is a health program/activity
- Applies § 1557 to short term limited duration plans and limited benefit plans
- Applies to third party administrators and PBMs

Section 1557:
Discriminatory Benefit Design

2022 Proposed Rule: Discriminatory Benefit Design

Builds upon NBPP examples of presumptive discriminatory design

- Cost sharing
- Medical necessity definitions
- Narrow networks
- Drug formularies
- Adverse tiering
- Utilization management
- Exclusions
- Visit limits
- Waiting periods
- Service areas
- Coercive wellness programs

Section 1557: Prescription Drug Access

2022 Proposed Changes - Rx’s

- Applies to PBMs
- Benefit design includes coverage, exclusions, and limitations of benefits; prescription drug formularies;
  - cost sharing (including copays, coinsurance, and deductibles)
    - Placing all or almost all drugs to treat a condition on the highest tier
  - utilization management techniques (such as step therapy, prior authorization, durational or quantity limits)

2022 Proposed Changes - Rx’s

- Acknowledges UM is “standard industry practice.. but must be applied in a neutral, nondiscriminatory manner”
- Potential Discrimination
  - Excessive use or administration of utilization management tools that target a particular condition
    - Rx formularies that place utilization management on most or all drugs that treat a particular condition regardless of their costs that don’t do this for other conditions.
- Where there is alleged discrimination, must be a legitimate, nondiscriminatory reason, based on clinical evidence

Need for Enforcement - Rx’s

- State Insurance Regulators, CMS & OCR must ensure compliance w/laws & regulations (1557 & EHB)
  - Plan reviews, approvals, & complaints
- **North Carolina Blue Cross/Blue Shield**
  - Place almost all HIV Rx’s, including generics, on highest tiers, all w/quantity limits
  - Complaint filed
    - No action by state insurance commissioners
    - OCR initiated review after plan corrected drug tiering, bought issuer reasoning that plan was based on clinical practices

Need for Enforcement - Rx’s

- **Community Health Choice Texas**
  - Doesn’t meet treatment guidelines
    - Excludes many antiretrovirals
    - Breaks up single tablet regimens
    - Covers old & discontinued drugs
  - Places drugs on highest tier
  - Complaint filed w/CMS, inadequate response & actions
- **Without enforcement, race to the bottom & jeopardize treatment nationwide**

Section 1557:
Scope of Sex Nondiscrimination Protections

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Restoration of the Full Scope of Sex Nondiscrimination Protections

- **2016 rule:**
  - Gender identity, sex stereotypes, and pregnancy, included under the definition of sex
  - Specific examples of gender identity nondiscrimination in coverage and care
  - Followed previous action by ~20 state regulators to prohibit discrimination against transgender people, particularly in benefit design
- **2020 rule:**
  - Eliminated gender identity, sex stereotyping, and pregnancy nondiscrimination regulatory protections
  - Also eliminated sexual orientation and gender identity (SOGI) protections from various CMS rules

Restoration of the Full Scope of Sex Nondiscrimination Protections

- **2022 Rule:**
  - Based on the 2020 Supreme Court decision in *Bostock v. Clayton County,* re-establishes gender identity nondiscrimination protections under the basis of sex and adds sexual orientation
  - Re-establishes protections on the basis of sex stereotypes
  - Includes “pregnancy or related conditions”
  - Clarifies that sex-based distinctions are allowed, but only if they cause *de minimis* harm to beneficiaries or patients
  - Clarifies that religious/conscience exemptions will be considered on a case-by-case basis by OCR under existing federal laws
  - Does not require providers to perform services outside of their scope of practice or area of specialty
  - Re-establishes CMS regulations that were eliminated by the 2020 rule

Regulator and Industry Support for 2022 NPRM

- **In 2022, 21 state insurance regulators sent a letter to HHS in support of the changes in the 2022 NPRM related to sex discrimination:**
  - "The proposed changes to the 2020 rule will promote the goal of robust civil rights protections and nondiscrimination in coverage while providing additional clarity for the consumers we serve and the companies we regulate"
  - "We are also aware that the proposed changes to the rule are consistent with several federal court rulings that have explicitly found that the sex nondiscrimination protections in Section 1557 prohibit discrimination against LGBTQ people."
- **AHIP's 2022 comments state:** "We strongly support ensuring that appropriate gender-affirming care is available and accessible to enrollees. We [are committed] to ensuring benefit designs and coverage decisions reflect evidence-based guidelines and recommendations and do not restrict coverage related to gender identity."

Section 1557: Exceptions process and health care refusals

Proposals for Health Care Refusals

- No blanket exemptions from § 1557 for religious or other covered entities
- Establishes procedures for submitting requests for exemptions to Office for Civil Rights
  - “Fact-sensitive, case-by-case analysis”
- Rescinds 45 C.F.R. § 92.6(b), where 2020 Final Rule incorporated the Danforth Amendment, Title IX’s exemption for abortion-related services

Section 1557: What State Regulators Can Do

What State Regulators Can Do

- Ensure that insurers are aware of the new protections (for instance via release of bulletins and guidance)
- Review plans for discriminatory benefit design as part of certification process
    - This could include more in-depth review for particular service categories or conditions more likely to be subject to discriminatory plan design
- Review and revise the state's EHB benchmark plan selection to ensure it does not have exclusions or other benefit design features that contravene Section 1557's requirements
- Monitor and enforce compliance through complaint process, data calls, and market conduct exams
- Make data and reports from market conduct and other investigations public

Practical Tips for Reviewing Benefit Design

- Coverage exclusions that disproportionately affect certain populations
    - Gender affirming care, durable medical equipment
- Prior authorization criteria not clinically based
    - See Washington State's E2SHB 1357 requiring PA be evidence-based, updated at least annually and accommodate evidence regarding appropriate care for people of color and gender differences
- Racial bias underlying prescribing practices and automated decision-making systems making coverage determinations
- Overuse of co-insurance for certain medical conditions and persons with significant health needs
- Narrow provider networks that prevent access to specialty care
- Visit limits which cap coverage without regard for medical necessity

Questions?

Contact:

- Wayne Turner - turner@healthlaw.org
- Carl Schmid - cschmid@hivhep.org
- Kellan Baker - kbaker@whitman-walker.org
- Dorianne Mason - dmason@nwlc.org

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