



Adverse tiering and prescription drug access

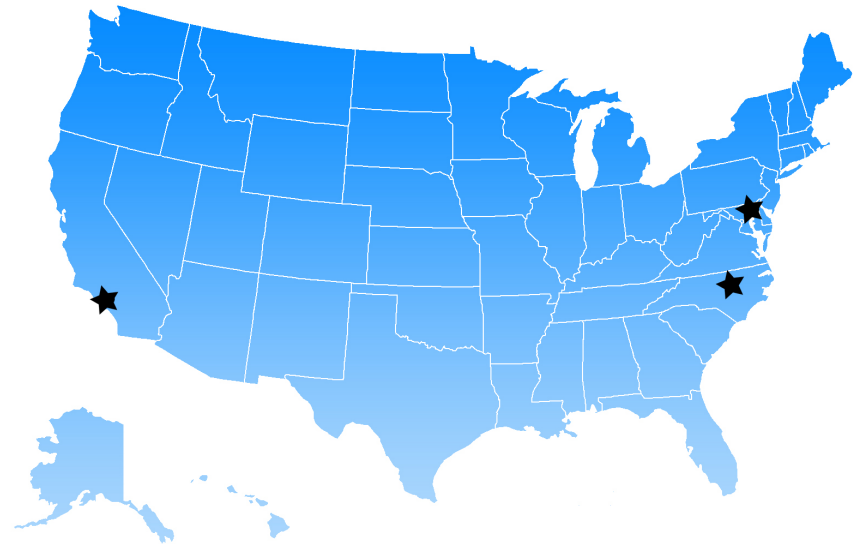
Wayne Turner, Senior Attorney

Hepatitis B United Coalition Summit

July 26, 2018

About NHeLP

- National non-profit organization committed to improving health care access and quality for underserved individuals and families
- State & Local Partners:
 - Disability rights advocates – 50 states + DC
 - Poverty & legal aid advocates – 50 states + DC
- National partners, *e.g.*
 - Network for Public Health Law
 - Center for Children & Families
- Offices: CA, DC, NC
- www.healthlaw.org



Health care coverage standards and protections

- Medicaid
- Affordable Care Act Protections
 - Plans subject to Essential Health Benefits
 - Qualified Health Plans (QHPs)
 - Plans subject to Sec. 1557 (ACA non-discrimination provision)
- Enforcement and filing complaints
- Protecting our gains

Medicaid

- Signed into law by President Johnson on July 30, 1965
- Replaced patchwork of local/state programs
- Title XIX of the Social Security Act
- Eligibility for low income children, pregnant women, persons with disabilities, parents/caretaker relatives, adults (Medicaid expansion)
- 74 million people currently enrolled



Medicaid outpatient prescription drugs

- Optional service but all states + DC cover
- All FDA-approved medications w/rebates
 - Medically accepted indications
 - Off label uses (supported)
 - No experimental
- Prior authorization ok, but limits/restrictions must be reasonable



Medicaid Due Process

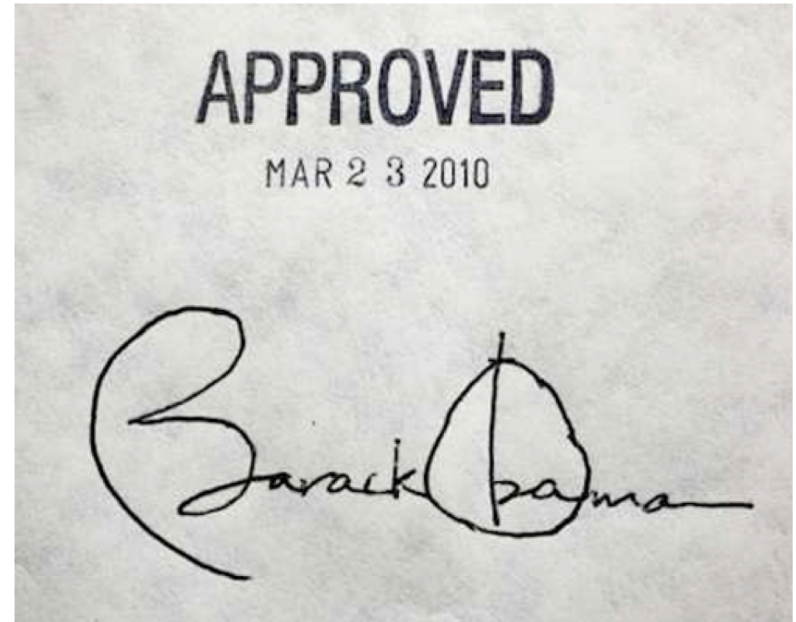
Medicaid applicants and recipients have rights to notice and administrative hearings when claims for assistance are denied or not acted upon with reasonable promptness.

Forums for enforcement

- Administrative complaint/appeal
 - Medicaid – Administrative fair hearing
 - Managed Care – Internal grievance or appeal
- State courts
- Federal courts



Patient Protection and Affordable Care Act



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 assistance

10 EHB categories of benefits

- ambulatory patient services
- emergency services
- hospitalization
- maternity & newborn care
- mental health and substance use disorder services, including behavioral health treatment
- **prescription drugs**
- rehabilitative and habilitative services and devices
- laboratory services
- preventive and wellness services, including chronic disease management
- pediatric services, including oral and vision care

Essential Health Benefits

- Plans sold on ACA marketplaces, small group plans (50 or fewer employees) **must cover** the EHBs
- Large group market plans, self-insured group health plans, Association Health Plans, Short-term Limited Duration Plans, and grandfathered health plans are **not required** to provide EHBs

Essential Health Benefits Non-discrimination

Issuers are required to cover essential health benefits in individual and small group markets and are prohibited from discriminating based on:

<i>Age</i>	<i>Race</i>
<i>Expected length of life</i>	<i>Color</i>
<i>Present or predicted disability</i>	<i>National origin</i>
<i>Degree of medical dependency</i>	<i>Sex</i>
<i>Quality of life</i>	<i>Gender identity</i>
<i>A health condition</i>	<i>Sexual orientation</i>

42 U.S.C. § 18022(b)(4)(D); 45 C.F.R. §§ 156.125 & .200(e)

Qualified Health Plans (QHPs)

- Cannot discriminate on the basis of:

<i>Race</i>	<i>Age</i>
<i>Color</i>	<i>Sex</i>
<i>National origin</i>	<i>Gender identity</i>
<i>Disability</i>	<i>Sexual orientation</i>

42 U.S.C. § 18031(c); 45 C.F.R. 156.200(e).

- Cannot employ marketing practices that will have the effect of discouraging the enrollment of individuals with significant health needs. 42 U.S.C. § 18031(c)(1)(A); 45 C.F.R. 156.225(b).

Section 1557 Overview

- 42 U.S.C. § 18116 (Section 1557 of the Affordable Care Act)
- Prohibits discrimination on the basis of:
 - race
 - color
 - national origin - LEP
 - sex - including gender ID, (sexual orientation), pregnancy, sex stereotyping
 - age
 - disability - ADA amendments definition
- Incorporates by reference Title VI (race, color, national origin), Title IX (sex), Age Discrimination Act (age), and Section 504 of the Rehabilitation Act (disability)

Examples of Covered Entities under Section 1557

- Any program or activity that HHS administers
 - Example: Medicaid, Children's Health Insurance Program
- Any program or activity created under Title I of the ACA, including the health insurance exchanges, health plans, and contractors
- Any health program or activity, *any part of which* is receiving Federal Financial Assistance
 - A hospital to receives Medicare or Medicaid reimbursements
 - Any plan that offers a product that receives federal funding
 - Large employer plan provided by an insurer that offers Medicare Advantage plans

ADA Amendments Act of 2008

- Broad definition of disability –physical or mental impairment that substantially limits one or more life activities
 - **Major life activities** (e.g., manual tasks, seeing, hearing, eating, sleeping, walking, standing, speaking, learning, concentrating)
 - **Major bodily functions** (e.g., immune system, normal cell growth, digestive, bladder, neurological, respiratory, circulatory, endocrine)

2014 HIV Discrimination Complaint



THE AIDS INSTITUTE



FL Silver plans –

- Inadequate formularies
 - Failed to cover standard treatments (single tablet therapy)
 - Missing commonly used HIV meds
- HIV drugs on highest tiers
 - Generics on Tier 5
 - High cost sharing (incl. co-insurance)
 - Limits and restrictions

Does 1557 protect against discriminatory benefit design?

- ADA safe harbor
- National standards, monitoring, and enforcement
- OCR vs. CCIIO vs. State regulators

Section 1557 Final Rule

[A covered entity shall not] have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage.

45 C.F.R. § 92.207

“we do not affirmatively require covered entities to cover any particular treatment, as long as the basis for exclusion is evidence-based and nondiscriminatory.”

U.S. Dep't of Health & Human Servs., Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Health Programs or Activities Administered by the Department of Health and Human Services or Entities Established under Title I of the Patient Protection and Affordable Care Act, 45 C.F.R. Part 92, 81 Fed. Reg. 31376, 31435 (May 18, 2016).

Sec. 1557 Enforcement Mechanisms

- Administrative Complaints
 - File with Department of Health and Human Services (HHS) Office for Civil Rights (OCR)
 - State Insurance Commissioners
- Federal Litigation
 - Regulations make clear that Section 1557 authorizes an express right of action for an individual to file suit in federal district court
 - Both disparate impact **and** intentional discrimination claims
- Other Possible Enforcement Options
 - Marketplaces (certification process)
 - Center for Consumer Information and Insurance Oversight (CCIIO) at HHS

Filing an OCR Complaint

- You can file a complaint by mail, by fax, e-mail, or via the online OCR Online Complaint Portal
 - Include your name and contact information
 - When filing a written complaint by mail, you may use a pre-printed form from OCR or handwrite your complaint.
 - Language assistance services for OCR are available
- You must file the complaint within 180 days of when the discrimination occurred
 - This deadline can possibly be extended for “good cause.”

Tips for identifying discriminatory plan design

- Are there “good plans” that offer more balanced cost sharing/more comprehensive benefits? For services or prescription drugs, does the plan have unusually high
 - high cost sharing
 - prior authorization or step therapy requirements?
- Does the benefit design reflect ***standard treatment protocols*** for that condition?
- Availability of drugs (or services) based on ***nationally recognized clinical guidelines***?

SABOTEUR

Health Care Sabotage
*Trump Owns It,
Regardless of His Rhetoric*



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2017 attempts to repeal ACA and Cut Medicaid

- 32 million would lose health insurance
- \$ 1 trillion in cuts to Medicaid through block grants/per capita caps
- End Medicaid expansion
- Eliminate Essential Health Benefits



Sabotaging the ACA

- Refused to pay Cost Sharing Reductions (CSRs)
- Cut open enrollment and funding for outreach and navigators
- Ended federal compliance monitoring
- Limited special enrollment periods
- Assaulted on women's health services
- Misleading data and HHS anti-ACA propaganda
- Undermined Essential Health Benefits
- Repealed individual shared responsibility payment
- Weakened Medical Loss Ratio
- Allowed refusals of care
- Expanded "junk" health plans



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

Rectangular Snip

**Fiscal Year
2017**

Office for Civil Rights

*Justification of
Estimates for
Appropriations Committee*

Cases involving insurance present new issues. Examples include how to evaluate whether health plans' practices of setting specialty prices for drugs used to treat HIV/AIDS, discriminate based on disability; how to determine which conditions should be treated as comparators in evaluating whether a plan's exclusion of particular services for a medical condition is discriminatory;

HHS compliance monitoring: formularies

Table 1: Prescription Drug Formulary Findings or Observations

Review Methodology	Findings or Observations
Performance Testing	<ul style="list-style-type: none">▪ Issuer's online formulary omitted drug restriction requirements such as specific tier information.▪ Issuer's formulary design contained significant changes since certification.▪ Changes to drug list appeared to go beyond mid-year maintenance updates to drug coverage.

3.1.3 Best Practices

- Regularly review all formularies, especially when they are managed by a third party, to ensure that any mid-year changes conform to applicable regulations.
- Regularly review published formularies to ensure they include a current and complete list of all covered drugs, including any tier structure that has been adopted, and any restrictions to obtaining a drug.

<https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/2017-PY-Notice-Summary.pdf>

HHS compliance monitoring: benefit design

December 4, 2017

Table 4: Marketing and Benefit Design Findings or Observations

Review Methodology	Findings or Observations
Process Review	▪ No findings or observations were identified in this review area.

3.4.3 *Best Practices*

- N/A

<https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/2017-PY-Notice-Summary.pdf>

Search tools for plan comparisons

Ambetter From Sunshine Health - Ambetter Balanced Care 5 (2018)

Silver | EPO | Plan ID: 21663FL0130070

<p>Estimated monthly premium</p> <p>\$529.99</p>	<p>Deductible</p> <p>\$7,350</p> <p>Individual Total</p>	<p>Out-of-pocket maximum</p> <p>\$7,350</p> <p>Individual Total</p>	<p>Copayments / Coinsurance</p> <p>Emergency room care: No Charge After Deductible</p> <p>Generic drugs: \$20</p> <p>Primary doctor: \$40</p> <p>Specialist doctor: \$80</p>	<p>Estimated total yearly costs</p> <p>ESTIMATE TOTAL YEARLY COSTS</p>	<p>Medical providers & prescription drugs covered</p> <p>Coverage details below</p> <p>SEE IF PROVIDERS & DRUGS ARE COVERED</p>
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Documents

- [Summary of Benefits](#)
- [Plan brochure](#)
- [Provider directory](#)

Dental

- ✘ Child Dental Benefit Not Included
- ✘ Adult Dental Benefit Not Included

\$7,410: Typical cost for a healthy pregnancy and normal delivery.

\$3,860: Typical yearly cost for managing type 2 diabetes for one person.

\$1,800: Typical cost for treatment of a simple fracture.

<p>Main Costs</p> <p>Health care cost</p> <p>Plan covers 70% of total average cost of care</p> <p>Total premiums for the year</p> <p>\$6,360</p> <p>List of covered drugs</p>	<p>Doctors & Hospitals</p> <p>Emergency room care</p> <p>No Charge After Deductible</p> <p>Inpatient hospital services (like a hospital stay)</p> <p>No Charge After Deductible</p>	<p>Other Services & Prescriptions</p> <p>Preferred brand drugs</p> <p>\$60</p> <p>X-rays and diagnostic imaging</p> <p>No Charge After Deductible</p>
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You can protect health rights

- Know your rights
- Enroll! Use benefits and services
- Complain/file grievances
- Story collection
- Mobilize, organize, resist





THANK YOU

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