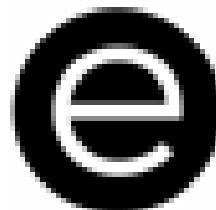


Stakeholders
Specialty Medication
Collaboratory

WELCOME

*Ensuring the ACA Works for People
with Serious and Chronic Conditions*

In Partnership with



I am essential





Today's Web Briefing will be Archived and Recorded

The PowerPoint slides will be posted at
www.chroniccareca.org and www.specialtyrxsos.org

The recording link to today's presentation will be sent to
everyone registered for this webinar.

Ask Questions At Any Time Via Chat Tools

After the presentation, our special guests will take questions from the audience via raise your hand and chat tools

Feel free to ask us questions at any time during the presentation.

Special Guests



Carl Schmid
Deputy Executive Director
The AIDS Institute
Washington, DC



Natalie Kean
Senior Policy Associate
The AIDS Institute
Washington, D.C.

ACA Nondiscrimination Protections

*Ensuring the ACA Works for People
with Serious and Chronic Conditions*

September 30, 2016

*Natalie Kean
The AIDS Institute*



THE AIDS INSTITUTE

ACA Non-Discrimination Protections

- Essential Health Benefits requirements
- Guaranteed Issue
- Marketplace rules:
 - As condition of participation, QHP issuers must not discriminate on basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation (42 C.F.R. § 156.200(e))
 - Issuers cannot employ marketing practices that have the effect of discouraging enrollment of individuals with significant health needs (42 C.F.R. § 156.225(b))
- Section 1557

ACA Section 1557

“[A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from 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, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title 1 (or amendments).”

42 U.S.C. § 18116

Who is Protected

- Section 1557 prohibits discrimination on the basis of:
 - **race**
 - **color**
 - **national origin** – immigration status & limited English proficiency
 - **sex** - gender identity, (sexual orientation), pregnancy, sex stereotyping
 - **age**
 - **disability** - ADA amendments definition
- By incorporating existing civil rights laws:
 - Title VI of the Civil Rights Act of 1964 (race, color, national origin),
 - Title IX (sex),
 - Age Discrimination Act (age), and
 - Section 504 of the Rehabilitation Act (disability)

Who Must Follow 1557

- Programs & activities receiving federal financial assistance (except Medicare Part B)
 - Any health plan offered by an issuer that receives any federal financial assistance (FFA)—QHPs, Medicare plans
 - Facilities receiving Medicare or Medicaid reimbursement
- Programs & activities created under Title I of ACA
 - Federally-Facilitated Marketplace & all state-based Exchanges/Marketplaces
 - Contractors (e.g., assisters, navigators, firms)
- Programs & activities that HHS administers
 - Medicare, Medicaid, CHIP, CDC, IHS, etc.

1557 Protections Related to Insurance

Final 1557 Regulation (45 C.F.R. § 92.207) prohibits Issuers from discriminating on the basis of race, color, national origin, sex, age, or disability in providing or administering health insurance or coverage, including:

- (1) Denying, canceling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage,
- (2) Denying or limiting coverage of a claim
- (3) Imposing additional cost sharing or other limitations or restrictions on coverage
- (4) Having or implementing marketing practices or benefit designs that discriminate in a health-related insurance plan or policy, or other health-related coverage

Discriminatory Benefit Design

- Final 1557 Rule clearly prohibits discriminatory benefit design but did not define it.
- HHS will review benefit design on a case-by-case basis
- Reiterated examples of potentially discriminatory benefit design features:
 - placing most or all prescription medications that are used to treat a specific condition on the highest cost tiers (a.k.a “adverse tiering”),
 - applying age limits to services that have been found clinically effective at all ages, and
 - requiring prior authorization and/or step therapy for most or all medications in drug classes regardless of medical evidence.
- Declined to recognize narrow provider networks as potentially discriminatory

Enforcement

- Proactive through Plan Certification Process
 - Center for Consumer Information & Insurance Oversight (CCIIO), U.S. Department of Health & Human Services (HHS)
 - State Departments of Insurance (DOI)
- Reactive through Complaints or Lawsuits
 - 1557 Administrative Complaint with Office for Civil Rights, HHS
 - 1557 provides private right of action to sue in federal court
 - » Do not rush to sue! Bad facts + bad lawyers = bad law
 - » Risk of unintended results
 - State DOI Complaints (options & process vary by state)

Example of 1557 Complaint re Discriminatory Design



- 4 of 10 Issuers placed all HIV Rx on highest tier, a.k.a. “adverse tiering” with 40 – 50% co-insurance
- OCR has not responded but added discriminatory benefit design to final 1557 Rule
- National attention to the issue
- Florida Insurance Commissioner took action that has improved HIV Rx coverage

Ongoing Impact of 1557 Complaint in Florida

- FL Insurance Commissioner's memo to issuers:
 - find plans discriminatory if cost-sharing for HIV Rx not as favorable as benchmark plan
 - review all plans for all Rx for discrimination through formula design, benefit design, or medical management techniques and decertify plans that engage in these practices
 - require all plans to attest to non- discrimination
 - 2017--added review of multiple conditions for formulary adequacy & adverse tiering:
 - HIV
 - hepatitis C
 - breast & prostate cancers
 - rheumatoid arthritis
 - bipolar disorder & schizophrenia
 - Diabetes
 - Multiple Sclerosis

Florida's 2017 Plan Review

Chronic Conditions Template for Plan Year 2017 Filings

Company Name: _____
IC Company Code: _____
NAIC Group Code: _____
HIOS Issuer ID: _____
Formulary ID: _____

of Rx
covered in
each tier

List all Rx on formulary to
treat each condition

*Please read instructions completely before completing the template.

Chronic Conditions*	Prescription Tiers					Available Drugs Please list all drugs (by their RXCUI) which are available in this formulary for the treatment of each of the specified chronic conditions and separate entries with commas. The information entered into this column is not required to be differentiated by tier.	
	Enter the number of drugs covered in each tier.						
	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5+		
Bipolar Disorder							
Breast Cancer							
Diabetes							
Hepatitis C							
HIV							
Multiple Sclerosis							
Prostate Cancer							
Rheumatoid Arthritis							
Schizophrenia							

Additional 1557 Complaints

- 1557 Complaints have been filed on pregnancy coverage, gender rating, mistreatment of transgender individuals, and HIV/AIDS
- On September 6th, Harvard Center for Health Law & Policy Innovation partnered with local advocates to file OCR complaints against 14 insurers in 8 states (AL, GA, IL, LA, PA, TX, TN and WI)
 - HIV Rx focused
 - Allege adverse tiering, failure to cover recommended Rx
 - Plan to file complaints in five additional states (MI, MN, OH, OR and SC)

Conclusion

- ACA's nondiscrimination protections are broad
 - Although discriminatory benefit design examples not codified
- Challenge now is enforcement
- Advocacy is Key!
 - Keeping an eye on plan design
 - Filing complaints with OCR
 - Involving state insurance commissioners
 - Meeting with Issuers

Resources

- HHS Office for Civil Rights
 - Final Rule & Fact Sheets:
<http://www.hhs.gov/civil-rights/for-individuals/section-1557>
- National Health Law Program (NHeLP)
 - Issue Brief on 1557 Final Rule:
<http://www.healthlaw.org/publications/1557-Highlights#.V-IKsvArLIU>

Thank you!

Natalie Kean
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Progress Made & Next Steps in Securing Access to Rx:

*Ensuring the ACA Works for People
with Serious and Chronic Conditions*

September 30, 2016

Carl Schmid
Deputy Executive Director
The AIDS Institute



THE AIDS INSTITUTE

Efforts to Ensure ACA Works

- ACA has great benefits
- But, need to ensure it works for people with serious and chronic health conditions
 - Coalition efforts
- Concerns with health plans:
 - Transparency
 - Limited Benefits (Rx)
 - Excessive Utilization Management
 - Patient Cost-sharing

Transparency

- CClIO Requiring Better Transparency
 - Direct Links to formularies
 - Can review in the window shopping & plan selection phases
 - Not all formularies organized the same way
 - Would be great to require a Rx look up tool
 - Some plans and states utilize
 - Formularies must include Tier level
 - But need plan information for cost-sharing amount
 - And with co-insurance, no idea of the dollar amount

Transparency

- CClIO Requiring Better Transparency (cont.)
 - Must include prior authorization, quantity limits
 - But hard to determine what are the prior authorizations
 - Plans must submit data in machine readable format
 - Outside 3rd parties can use
 - Direct links to Providers

Limited Benefits

- Criteria for Rx Coverage
 - A plan must have a minimum of one drug per USP class or at least the same number of drugs per class as the State's benchmark plan
 - State benchmarks vary
 - USP did not initially cover combination Rx
 - No process to add in newly approved Rx
 - Require Pharmacy and Therapeutics Committee (proposed in 2015 but begins in 2017)
 - Must meet quarterly
 - Must consider scientific evidence & treatment guidelines
 - Review utilization management
 - Must consider new Rx
 - But, "Wait and See" attitude on Implementation

Limited Benefits

- CClIO Will Review for Clinical Appropriateness of Rx Coverage
 - Included in 2017 “Letter to Issuers”
 - Will review covered drugs recommended by nationally-recognized clinical guidelines for:
 - bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia
 - Will also review for cost-sharing
 - But just 9 conditions!
 - May add more in the future

Other Improvements

- Improved Exceptions Process
- Prohibit Mail-order only Plans (Beginning 2017)
- Looking into mid-year formulary drug changes
 - Additional work needed

Plan Reviews

- Included in 2017 “Letter to Issuers”
 - Formulary Outlier Review for:
 - High Number of Prior Authorizations
 - Step Therapy Process
 - Adverse Tiering
 - Placing Rx on high tiers
 - Potentially discriminatory

Solutions to High Cost-Sharing: State Responses

- Limit patient co-pays:
 - DE: \$150 limit for Specialty Drug co-pays, prohibits all drugs in one class on Specialty tier
 - LA & MD: \$150 co-pay limit
- Standard Benefit Option
 - CA: Limits co-pays depending on Tier and Metal level; \$250 limit, except \$500 in Bronze Plans
- Prohibit Specialty Tiers
 - NY: patient cost can't be more than non-preferred brand

Other State Responses

- CO: Allows plans to use co-insurance but issuer also must offer plans that use co-pays; deductible does not apply to Rx, co-pays can be spread out over year
- MT: Each issuer must offer a plan with co-pays that are exempt from deductible; cost sharing in each plan must be graduated in all tiers

Cost Sharing Solutions

- CCIIO Proposed Standard Benefit Option
 - Voluntary, plans encouraged to offer & will highlight “Simple Choices” for consumers in 2017
 - Limits co-pays, at reasonable levels, depending on metal level and tier
 - Exempts Rx from deductible (except most Bronze tiers)
 - But, allows co-insurance 25-45% for Specialty Tier and all Bronze (except generics)
- Families USA Milliman Study
 - *“New Health Plans Allow People to Visit Doctors and Fill Prescriptions without Paying a Deductible with Little Impact on Premiums”*

Proposed “Simple Choices” in 2018

- CCIIO Proposed changes in Notice of Benefits and Payment Parameters
 - Remain voluntary
 - Adds Options for States that Limit Rx co-pays
 - Keeps Same Design for Standard Option
 - Still includes High Co-insurance for specialty tier & most Bronze Rx
 - Subjects specialty tier Rx to the deductible
 - But institutes separate Rx deductible
 - Why not just limit co-pays?
 - Comments Due October 6

Congressional Efforts

- Patients' Access to Treatments Act (HR 1600)
 - Bipartisan--Introduced by Reps. David McKinley (R-WV) and Lois Capps (D-CA)
 - 97 co-sponsors
 - Plans can't charge more for Rx on Specialty Tier than Non-preferred tier
- Senate Bipartisan letter
 - Led by Sens. Chris Murphy (D-CT) & Shelly Moore Capito (R-WV)
 - Signed by 8 additional Senators
 - Asks Senate Health Committee to review patient's perspective on high cost-sharing

Federal Solutions

- Risk Adjustment:
 - Plans paid for carrying sicker patients
 - In 2014, CCIIO readjusted \$4.6 billion among the plans
 - Currently only considers certain diagnoses
 - In 2018, proposing to add Rx usage
 - Limited set of 11 health conditions
 - Should help better reward plans for sicker patients & hopefully reduce high patient cost-sharing
 - Comments Due October 6

State & Federal Enforcement

- Annual Review of Plans Prior to Certification
 - Adequate Tools and Templates Needed
 - For States and Federal Government
 - Adverse Tiering Tool in development
- CClIO Grant to States
 - \$22 million for State Insurance Regulators
 - Can review for potential discrimination in plan design
 - Who will apply and receive?

The Future?

- 2018 Proposed Benefit and Payment Parameters Rule
 - I Am Essential Sign-on letter: <http://bit.ly/2dGycA4>
 - Sign-on by October 5 at <http://bit.ly/2cTkFkp>
- Expecting Release of 2018 “Letter to Issuers”
- 2017 Plan Review
 - CClIO & States Depend on us to identify issues
- 2016 Elections
 - Ensure Patient Protections Continued & Enforced
- Debate over the ACA
- Continued Need for Patient Voice

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THANK YOU!

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Open Line Questions



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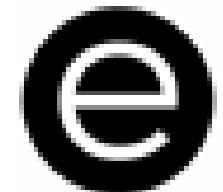


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