Progress Made & Next Steps in Securing Access to Rx:

Ensuring the ACA Works for People with HIV and Hepatitis

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Efforts to Ensure ACA Works

- ACA has great benefits
- Ensuring it works for people with HIV, hepatitis and other chronic conditions
  - Coalition efforts
- Concerns with health plans:
  - Transparency
  - Limited Benefits (Rx and Providers)
  - Excessive Utilization Management
  - Patient Cost-sharing
  - Discrimination

Transparency

- CCIIO 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
      - Healthcare.gov tool allows filtering plans by Rx coverage
        - Only during window shopping
        - Does not show tiering or cost-sharing
  - Formularies must include Tier level
    - But need plan information for cost-sharing amount
    - And with co-insurance, no idea of the dollar amount

Transparency

- CCIIO Requiring Better Transparency (cont.)
  - Must include prior authorization, quantity limits
    - But hard to determine what the prior authorizations are
  - Plans must submit data in machine readable format
    - Outside 3rd parties can use
  - Direct links to Providers
    - Essential Community 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
    - CCIIO saying "Wait and See" on Implementation

Limited Benefits

- CCIIO 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)
- Monitoring mid-year formulary changes but still need to address

Plan Reviews

- Included in 2017 “Letter to Issuers”
  - Formulary Outlier Review for:
    - High Number of Prior Authorizations
    - Step Therapy
  - 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 the Basic one
    - 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?

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

Section 1557

"an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.)…or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), 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…"

Additional Non-discrimination Requirements

- Qualified Health Plans may "not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs."

42 U.S.C. § 18031(c)(1)(a))

Discrimination Enforcement

- Issued Section 1557 ACA Non-discrimination rules
  - Plan design can be discriminatory
    - Did not include examples in regulation
    - Cited potential examples in footnote (were in previous CCIIO Announcements)
      - Placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers
      - Requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence

Discrimination Enforcement

- Letter to Issuers (2017):
  - **CMS cautions issuers to avoid discouraging enrollment of individuals with chronic health needs**. For example, **if an issuer does not cover a single-tablet drug regimen** or extended-release product that is customarily prescribed for HIV patients and is just as effective as a multi-tablet regimen, absent an appropriate reason for the exclusion (such as a substantial difference in the cost of the two regimens), such a plan design might effectively discriminate against, or discourage enrollment by, such HIV patients who would benefit from such innovative therapeutic options

Discrimination Enforcement

- No decision on Florida HIV case
- Additional complaints filed in 8 States (September 6th)
- Turn to states to enforce
  - Role of State Insurance Commissioners
- Need Federal Enforcement, as well
  - And Additional Regulations and Guidance

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 conditions, includes HIV & Hepatitis C
  - 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
- CCIIO 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 and "Letter to Issuers"
- 2017 Plan Review
  - CCIIO & States Depend on us to identify issues
- 2016 Elections
  - Ensure Patient Protections Continued & Enforced
- Debate over the ACA
- Debate over Drug Pricing

THANK YOU!

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