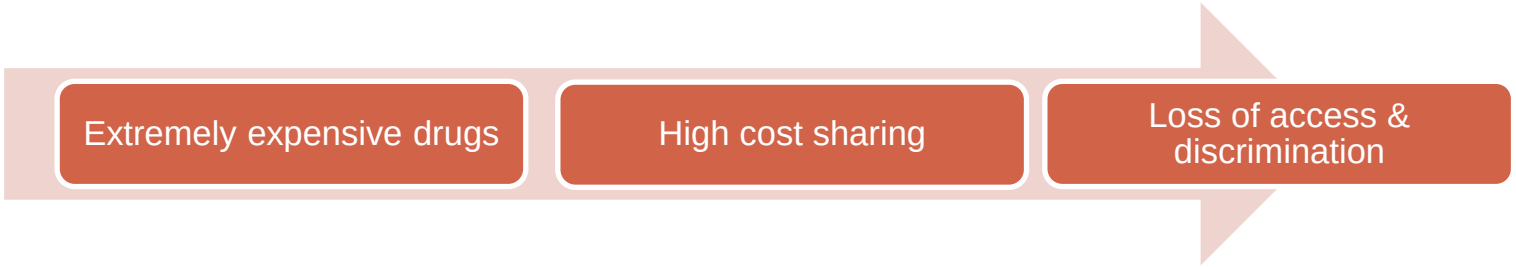
PROJECT INFORM

Access to High Cost Drugs

“Specialty” Drug Costs & Access

- Pharmaceutical companies aren’t coming to the table in a meaningful way
- Extremely high priced drugs make it difficult for insurance plans to keep drug cost sharing affordable prices & keep premiums affordable
- Plans need to be able to negotiate drug prices with pharmaceutical companies; tiering allows this
- Outcome: the consumer loses



2016 Covered California (CC) Requirements

- Convened a ground-breaking specialty drug workgroup
- Actions thus far for CC plans:
  - Expanded formulary transparency and access (in addition to actions required by SB1052 for all plans to have standard formulary information posted):
    - Plans will have to have an opt out retail option for mail order
    - Plans will provide an estimate of range of cost for specific drugs
    - Formularies include all of the covered drugs to treat HIV/AIDS, Hepatitis C, RA, MS, & Systemic Lupus Erythematosus
    - Exception process written clearly on formulary
    - Dedicated pharmacy customer services line

2016 CC Requirements (Cont.)

- Standardize the formulary tier definitions
- If there are three or more treatment options for a condition, at least one drug must be on Tier 1, 2, or 3
  - Specifically aimed at reducing cost burden for HIV/AIDS, Hepatitis C, RA, MS, and Lupus
  - Concern with HIV or hepatitis C is that people need specific drugs.
- Assess impact of implementation of caps on co-insurance costs
  - Impact on immediate and long term premium costs
  - Recommendation to Board in May 2015

SB1052 – Formulary Transparency

- As of January 1, 2015, plans must post formularies accessible to potential and current enrollees
  - Must be updated monthly
- By January 1, 2017, CDI and DMHC will jointly develop a standard formulary template including:
  - Cost sharing and utilizations controls
  - Difference between medical and prescription drug benefits
  - Process & steps to obtain non-covered drugs
- If feasible, require information on cost sharing associated with co-insurance
- Working group formed to implement provisions

AB 339 – Health Care Coverage: Outpatient Drugs

- Any CA plan that covers prescription drugs must cover all medically necessary drugs
- Plans must demonstrate that cost sharing for a medically necessary drug will not discourage adherence
- Demonstrate that formularies do not discourage enrollment or reduce the benefit generosity for those with health conditions
- Plans must cover single tablet regimens (STRs) and extended release formulations
  - unless they can demonstrate lower clinical efficacy; for STRs do not improve adherence
- When standard of care includes more than one treatment, most or all drugs can not be included on the highest cost tier
- Individual coverage formularies must be the same or comparable to group plans
- No cost sharing for one drug can be more than 1/24 of the maximum out-of-pocket cap for the plan year ***for self – coverage only*** ($275 for 2015)

AB 463 – Pharmaceutical Cost Transparency Act

- Manufacturers of drugs with a cost of $10,000 or more annually or per course of treatment must:
  - File a report with the Office of Statewide Health Planning and Development on drug production costs, including:
    - Cost of research and development
    - Clinical trial and regulatory costs
    - Material, manufacturing, and administration costs
    - R & D or other costs paid by other entities
    - Marketing and advertising
    - History of cost increases
    - Financial assistance provided through patient assistance programs
  - The Office issues report to the Legislature
    - Also posts report to its website

Access for People with HIV and hepatitis C and those at risk

- We still have 4 outlier plans in CC where most or all HIV drugs tiered at highest levels
  - Drugs tiered at this level have co-insurance between 30 and 10%
- Most, if not all, plans have all effective hepatitis C drugs on the specialty tier
- Most people with HIV or hepatitis C take multiple drugs
  - Adherence to an optimum regimen can be out of reach
  - Most studies show that cost sharing at or above about $250 a month seriously impacts adherence
- HIV and hepatitis C disproportionally affect lower income people, people of color, homeless, transgender people, young gay men and young people who inject drugs
- HIV and hepatitis C are infectious diseases
  - High cost sharing can put treatment as prevention (HIV), cure as prevention (hep C) and PrEP and PEP out of reach
  - Threat to population and community health