Session 080: Measuring the Impact of Emerging Healthcare Technologies

SOA Antitrust Compliance Guidelines
SOA Presentation Disclaimer

2019 ANNUAL MEETING & EXHIBIT

Measuring the Impact of Emerging Health Technologies

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October 29th, 2019

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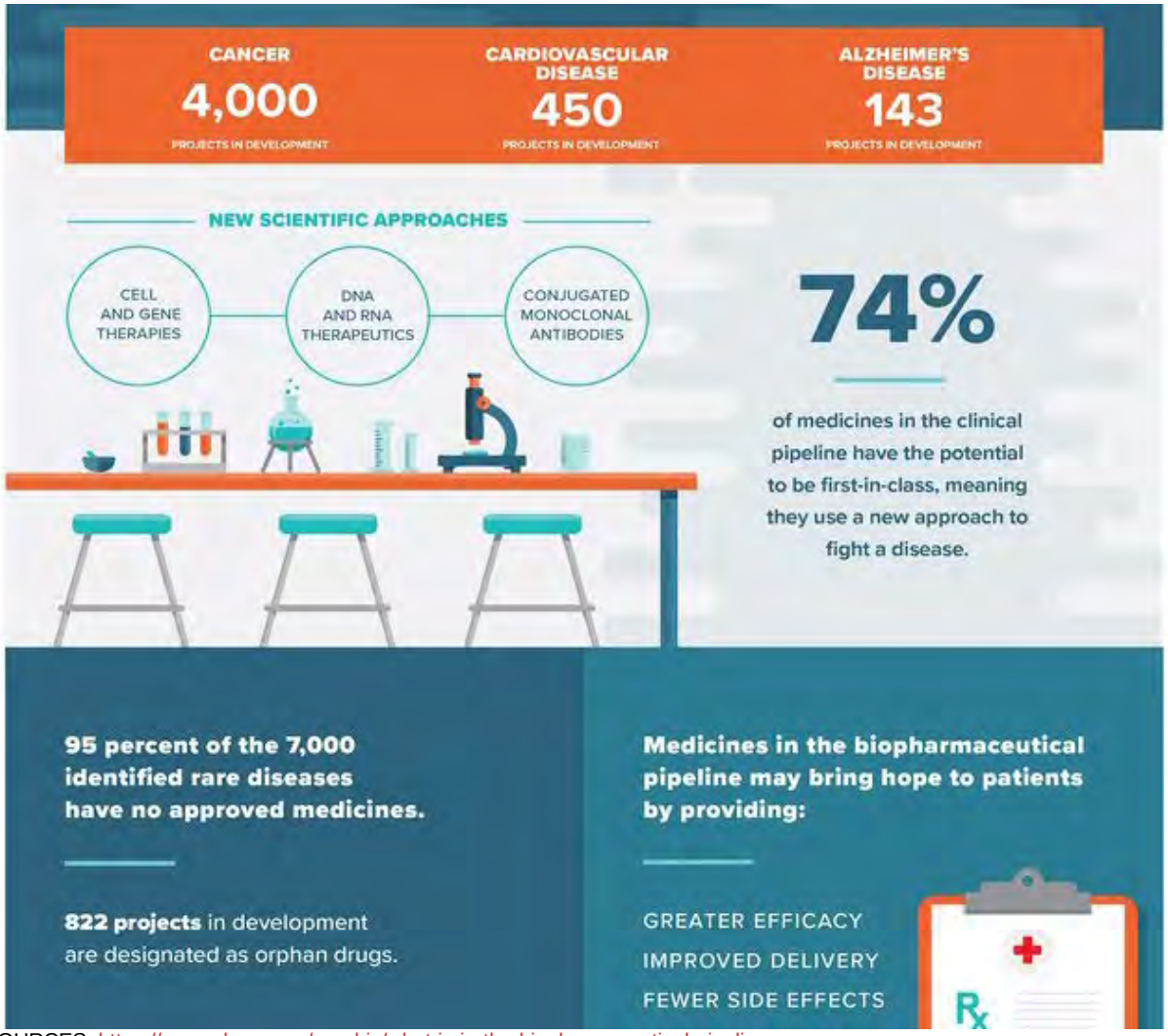
Health Technology Landscape

Over 15,000 health technologies are in development

U.S.–based biopharmaceutical companies invest $75 billion a year

By 2020, 9 of the 10 top-selling drugs will be specialty drugs and account for 50% of drug spend.



SOURCES: https://www.phrma.org/graphic/what-is-in-the-biopharmaceutical-pipeline, https://www.phrma.org/industryprofile/2018/, https://www.covermymeds.com/main/insights/scorecard/specialty/

New Therapies Result In…

Increases in Utilization

Increases in Unit Cost

Change in Cost Mix

Proactive pipeline monitoring is the key to anticipating the impact of new drugs

Process of Evaluating Pipeline Technologies

Horizon Scanning
- Technology identification
- Anticipated approval within 2 years
- Disruptive potential

Research and Clinical Content
- Extensive use of primary references, peer-reviewed journal articles, trial data
- Peer review of written materials by clinical experts

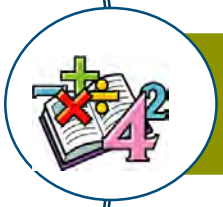
Data Analysis and Research for Modeling Assumptions
- Reconciliation between external and internal data sources
- Assumption-setting by clinical and actuarial staff

Projection Modeling and Customization
- View from both Private Payer and Medicare perspectives
- Peer review by actuarial staff

Requisite Expertise

Writing and editing: Clinically-trained writers, MPHs, peer reviewers

Modeling: Health economists, actuaries, computer programmers, clinical staff



Actuarial: Certified ASA and FSA modelers, peer reviewers

Clinical: MDs, PharmDs, medical and pharmacy directors, MPHs

Certified Coding: Health information management specialists

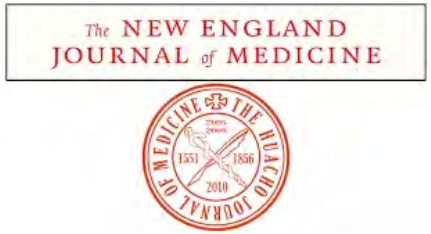
What is Horizon Scanning?

- **Horizon scanning aims to identify emerging medical technologies that are expected to have a significant clinical and economic impact**

Includes:

- New Medications
- New Medical Devices
- New Cell, Gene, and Stem Cell Therapies
- New Screening, Diagnostic, and Pharmacogenomic Tests
- Brand-to-Generic, Brand-to-OTC, and Brand-to-Biosimilar Switches

Potential Horizon Scanning Sources



Disruptive Technologies: Criteria

- Novel mechanism of action/first-in-class technology
- Large number of indications/potential indications
- New treatment for a large patient population
- Game-changing therapy for a disease with few, if any, effective interventions
- Improved safety and/or efficacy over standard-of-care or available therapies
- More convenient route of administration than existing treatments
- Potential to reduce costs
- High expected cost
- New or expanded screening or treatment guidelines for a given condition
- Recognized by the FDA as constituting an important therapeutic advance
- Buzz/hype - Media/public interest

Challenges in Determining Potential Impact

- Size of Eligible Population
- Compliance Considerations
- Pending Trial Results

- Likelihood of Adoption
- Unknown Costs
- Regulatory Delays
- Reconciliation of Conflicting Information

Applications of Pipeline Research

Pipeline Research Aids In:

- Determining the likelihood of insurance coverage
- Proactive development of medical policies
- Proactive development of formularies
- Development of coding and administration guidelines
- Training and educating physicians to prescribe new treatments
- Preparing providers for changes in healthcare delivery

Actuarial Modeling of Pipeline Technologies

PMPM Forecasts

- By line-of-business (LOB), technology type, therapeutic class
- Pipeline Technologies
- Approved Technologies – new or expanded indications
- Revise Technologies

PHOTO: https://www.pexels.com/@breakingpic

Modeling Assumptions

Model Questions

1. Medical vs. Pharmacy Impact
2. Population Assumptions
3. Direct Costs
4. Offsetting Costs
5. Launch Date
6. Grade-In
7. Adoption Rate

Essential Data

- Medical and Pharmacy administrative claims and membership data
- Externally-published statistics

Modeling Assumptions: Medical vs. Rx Impact

Model Type

- Brand Drugs/Biologics
- Generics/Biosimilars
- Devices
- Tests

Medical vs. Pharmacy Impact

- Medical
  - IV infusions
  - Cell and gene therapies
  - Devices, procedures, and screening tests
  - Professionally-administered, subcutaneous injections
- Pharmacy
  - Oral prescriptions
  - Self-administered. subcutaneous injections

Modeling Assumptions: Population

Eligible Population

Pull one year of “annual prevalence” data using:

- LOB
- Diagnosis Codes
- HCPCS, J codes
- NDCs, AHFS class
- Exclusions

Utilization

Election Rate

- Low
- Medium
- High

Adherence Rates

Modeling Assumptions: Costs

Direct Costs

- Cost estimates use:
  - Currently-approved treatments with similar mechanisms of action
  - Sales projections
  - Dosing information
- Factors that impact direct costs
  - Size of eligible population
  - Competitive environment
  - First-to-market advantage
  - Route of administration
  - Professional and facility fees

Offsetting Costs

- Foregone costs
- Factors that impact offsetting costs
  - Add-on therapy vs. replacement therapy
  - Professional and facility fees

Modeling Assumptions: Timeline

Expected Date of First Impact

- FDA approval date
- Guideline implementation date
- Patent litigation/Generic market entry

Grade-In Period

- Varies for Rx vs. Medical vs. Devices
- Brand vs. Generic or Biosimilar

Value of Pipeline Analysis

Pipeline monitoring enables U.S. payers and pharmaceutical manufacturers to proactively manage various activities:

- **Trend Forecasting**
- **Medical Technology Assessment**
- **Management Strategy**
- **Medical Policy Development**

Thank you.

2019 ANNUAL MEETING & EXHIBIT

Challenges in Projecting Medicare Part D

Aaron Hahn, ASA, MAAA

October 29th, 2019

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2018 ANNUAL MEETING & EXHIBIT

Overview of Medicare Part D

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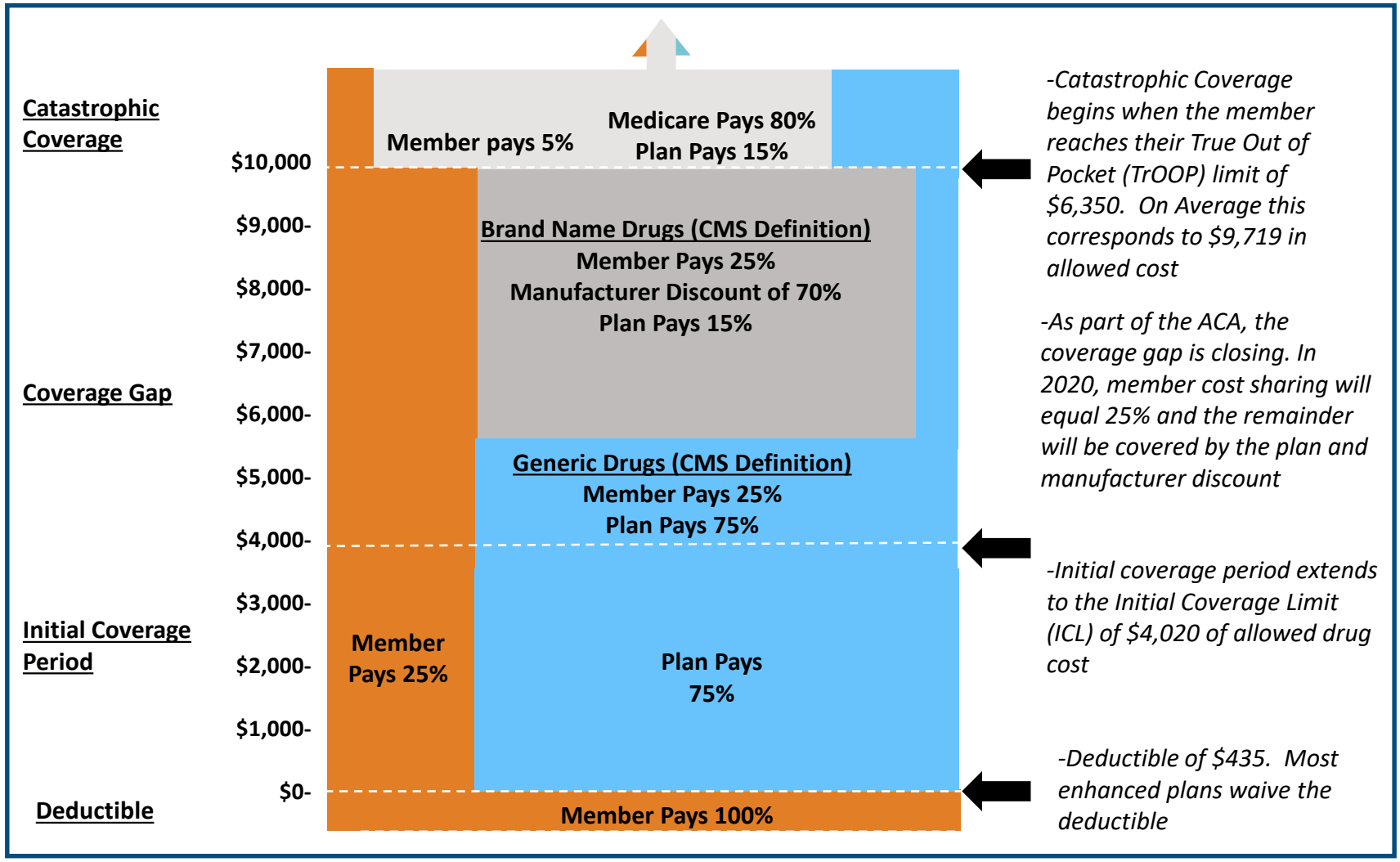
Agenda -
Part D is Complicated, Unintuitive, and Changing

- Overview/Refresher of Medicare Part D
- Examples of Unintuitive Results
- Past and Future Legislative Changes & Challenges

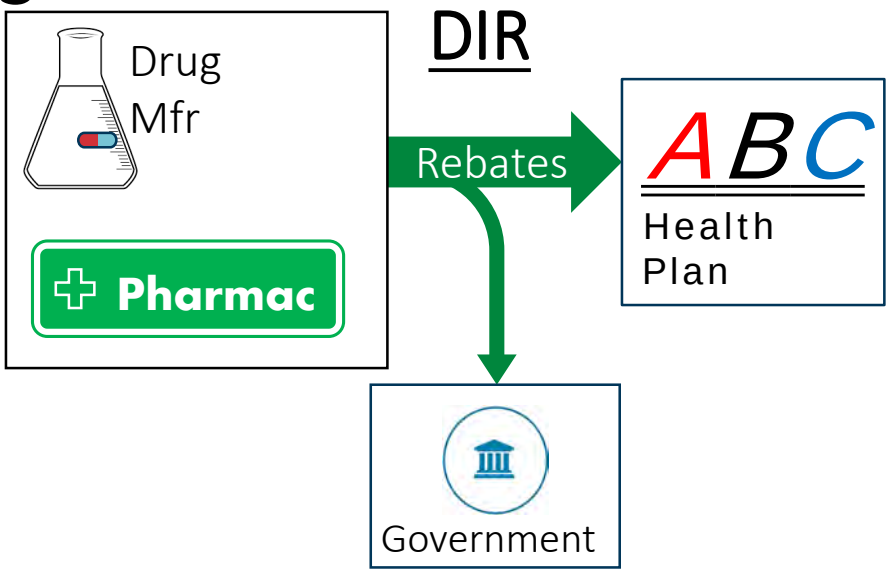
The Standard Part D Benefit Design

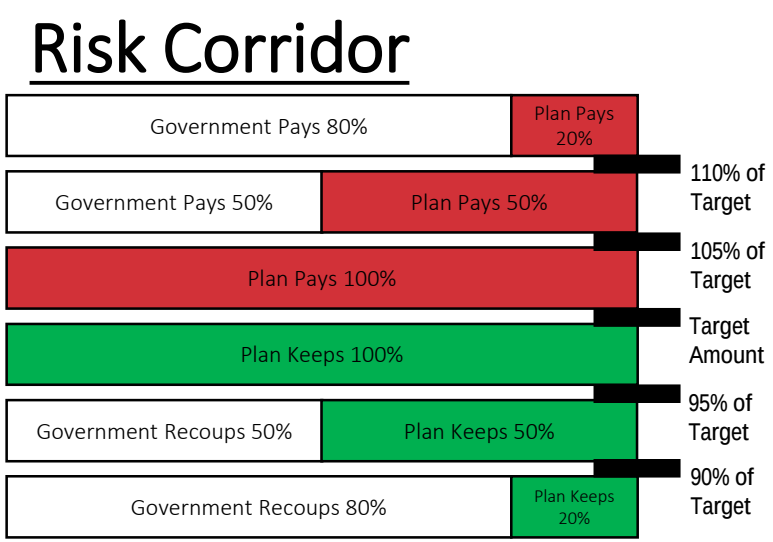


- Plans can layer on additional coverage or fixed co-pays but must be at least as good as the standard design
- *The impact of an allowed cost and cost sharing accumulator as well as different cost sharing by drug makes projections difficult*

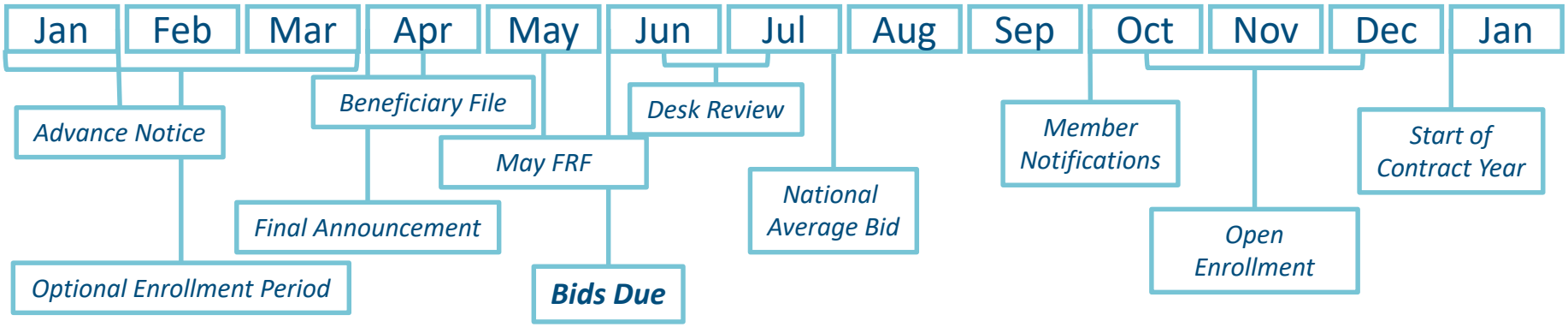
DIR and Risk Corridors

- Direct and Indirect Remuneration (DIR) - All transactions occurring outside the point of sale
- Rebates from pharmacy manufacturers for preferred formulary placement or exclusivity
- Rebates from pharmacies for preferred level co-payments to steer members to their stores
- CMS reduces final reinsurance payments to plans roughly based on the proportion of rebates associated with claims in the catastrophic phase
- CMS also provides a risk corridor for Part D plans at 50% outside +/- 5% and 80% outside +/- 10% of bid estimates
- *These multiple layers of offsetting transactions make predicting the impact of unexpected changes challenging to model*





Information Timeline for Bids



- Beneficiaries now have the option to switch MA plans or enroll in original Medicare within the first 3 months creating additional ambiguity
- Plans receive the "Final announcement" and Bid Pricing Tools from CMS less than two months before bids are due on the first Monday of June
- Plans must project the National Average Bid Amount (NABA) and Base Beneficiary Premium on the bid due date. Bid premiums are adjusted after those amounts are calculated.
- CMS Releases a Formulary Reference File in May that could require plan formulary adjustments within weeks of the bid due date

- *The timeline to complete projections for bids is rigid, compressed, and contains significant ambiguity.*

Examples of Unintuitive Results

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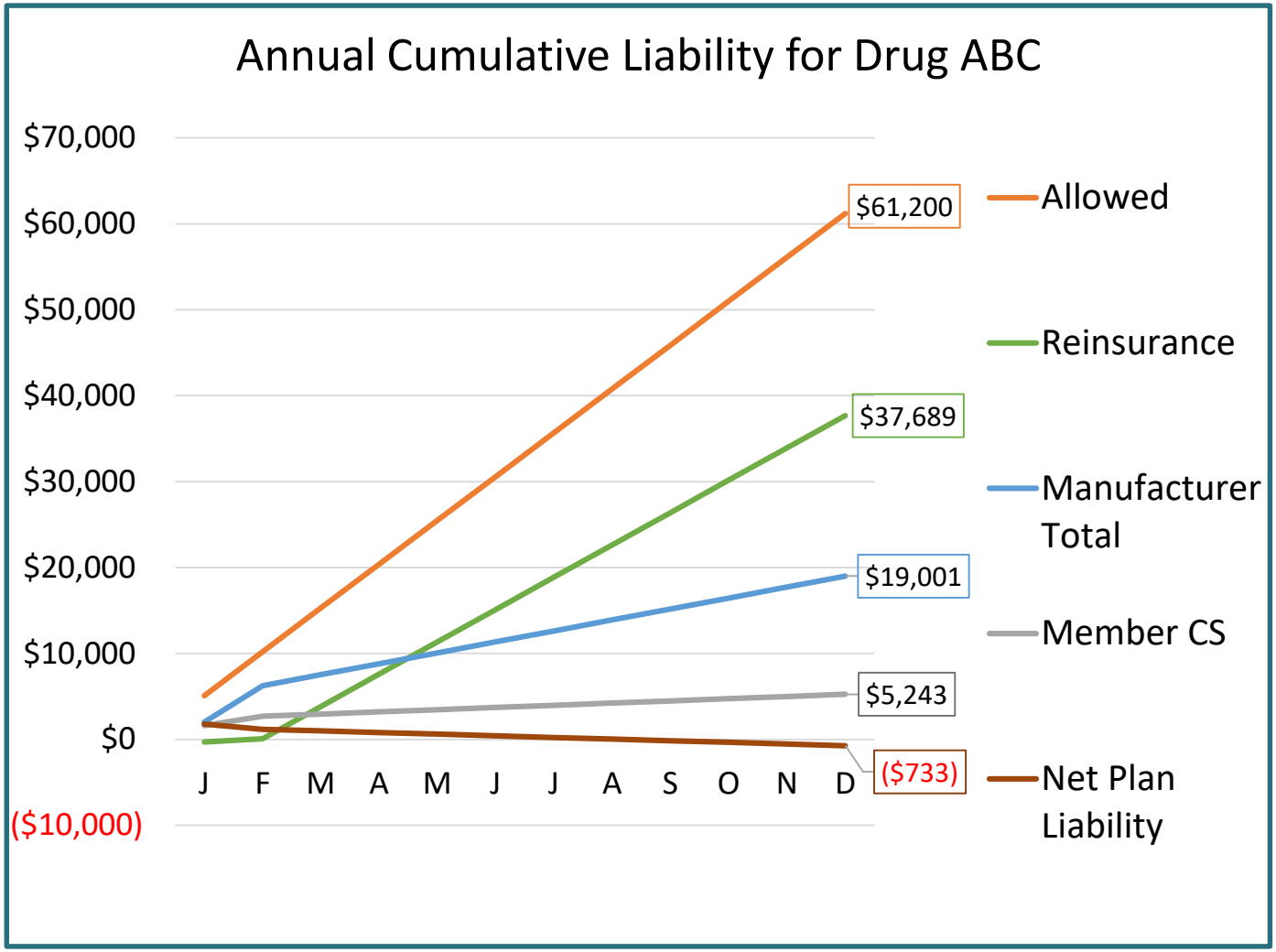
Negative Net Paid Claims

Drug "ABC" Assumptions:

- Taken chronically – one script per month
- Average Wholesale Price (AWP) is $6,000 per 30 day supply
- Plan discount is 15% off AWP
- Plan receives a rebate of 35% of AWP
- CY 2020 Plan Design with EA benefits
- Drug is covered at the specialty tier with 33% coinsurance in initial coverage



Increasing MAPD Revenue With Aggressive Part D Pricing

General Assumptions

- MA Benchmark of $850 PMPM
- Plan has 4 STARS – 65% rebate
- Projected Medical costs of $600 PMPM
- Projected Non-Medical Expenses of $100 PMPM
- $50 PMPM of cost sharing improvements and mandatory supplemental benefits
- Target premium of $0
- Part D Direct Subsidy of $10

Scenario 1: Conservative Part D Bid

- Part D Basic Premium = **$40**
- Part D Supplemental Premium = **$30**
- Total MA Rebate Allocation = $50 + $40 + $30 = **$120**
- Required MA Bid = $850 – ($120)/65% = **$665**
- Bid Margin = $665 – $600 - $80 = **-$15**
- MAPD Revenue = $665 + ($850-$665)*65% + $10 = **$795 PMPM**

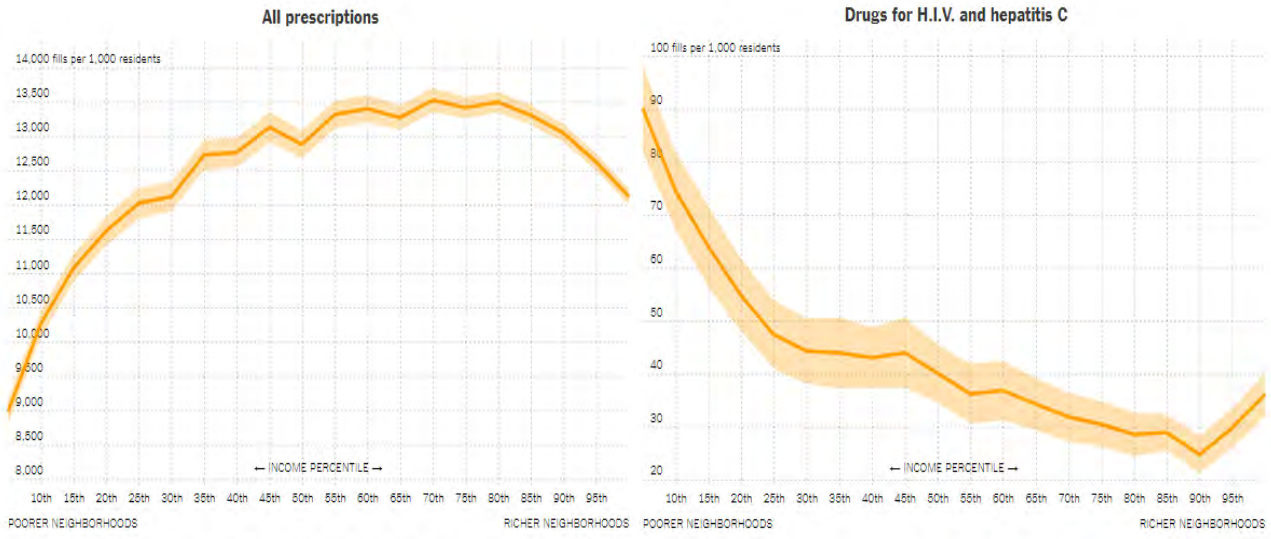
Scenario 2: Aggressive Part D Bid

- Part D Basic Premium = **$25**
- Part D Supplemental Premium = **$20**
- Total MA Rebate Allocation = $50 + $25 + $20 = **$95**
- Required MA Bid = $850 – ($95)/65% = **$704**
- Bid Margin = $704 – $600 - $80 = **$24**
- MAPD Revenue = $704 + ($850-$704)*65% + $10 = **$809 PMPM**

Actual Revenue will vary based on risk adjustment but the more aggressive Part D bid will generate more revenue. If actual Part D experience is worse than the bid, the plan will also benefit from the risk corridor for Part D. The actuary must use appropriate and supported assumptions in the development of bids.

Low Income Subsidies and High List Prices

- They company GoodRx examined the relationship between prescription drug utilization for different categories of drugs and the wealth of the patient's neighborhood.



- Certain classes of drugs were much more commonly used among people living in poorer neighborhoods.
- Because the Low Income Subsidy and cost sharing design protects LI beneficiaries from high costs, these types of drugs are less likely to face price competition than other classes of drugs.

Source: Quealy, K. & Sanger-Katz, M. (2019, February 7). The Prescription Drugs That Rich People Buy. *New York Times.* Retrieved from https://www.nytimes.com/2019/02/07/upshot/income-strong-predictor-drug-purchases-serious-diseases.html

Past and Future Legislative Changes & Challenges

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The Bipartisan Budget Act of 2018

- The ACA had proposed to "close" the coverage gap by 2020. Standard cost sharing would decrease to 25% across all drugs, although most plans have alternative benefits in Initial coverage so members would still see a coverage change when they hit the gap.
- The Bipartisan Budget Act, signed into law on Feb 10th, 2018, accelerated this by a year and increased the manufacturer discount in the gap from 50% to 70%.
- This resulted in an unanticipated modeling change for plans with a short time to ensure models were accurately set up for the change.
- Predicting the change to NABA was also a challenge, and we continue to monitor how manufacturers are adjusting to the increased Part D liability.

HHS Proposal to Modify Safe Harbor Rules - POS Rebates

- Several proposals have been made from members of both political parties to ensure members benefit from manufacturer rebates.
- Currently, plans use rebates to help keep premiums low and competitive
- The most recent proposal by HHS issued in January of 2019 would require rebates to be applied to the allowed cost at the point of sale.
- Applying rebates at the point of sale would benefit some members who take high cost drugs and pay specialty coinsurance or who have significant coverage in the gap and catastrophic benefit phases.
- The proposal would lower manufacturer liability from the Brand Gap Discount
- The government would lower it's liability for catastrophic reinsurance but would pay more in direct premium subsidies
- Members would also likely see increased plan premiums
- This proposal lacked details, and was left ambiguous through the entirety of the bid season. It was revoked in July after bids were completed for 2020.

Other Part D Proposals

- Allowing the US government to negotiate drug prices on behalf of Medicare
  - Currently banned under the Medicare Modernization Act (MMA) that established Part D
  - CBO has evaluated this three times (2004, 2007 and 2019) and concluded that it would have very small impacts on drug prices
- Modifications to the Part D Benefit Design
  - Establishing a Maximum Out of Pocket (MOOP) of $3,100 for 2022
  - Modify the catastrophic phase to be covered by Plans (60%), Government (20%) and Manufacturers (20%)
- Exclude Manufacturer Discount from the calculation of TrOOP
  - Large Savings for the government but cost increases for Seniors and Manufacturers
  - Could lead to unintended increases in list prices as manufacturers “make up” for increased gap coverage
- Require rebates for list price increases that exceed inflation
  - CBO projects savings for the government and beneficiaries but this could lead to higher launch prices from manufacturers


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