INFLATION REDUCTION ACT PLACEMAT

HOW HIGH CAN CMS SET MAXIMUM FAIR PRICE UNDER THE DRUG PRICE NEGOTIATION PROGRAM?

- 75% CAP
- 65% CAP
- 40% CAP

INFLATION-BASED REBATES
- PART D REBATE: MEASURED ANNUALLY (10/1-9/30)
- PART B REBATE: MEASURED QUARTERLY
- CALCULATIONS HAVE BEGUN [Q4 2022 – PART D; Q1 2023 – PART B]
- ANNUAL INVOICING
- NO EXCEPTION FOR DRUGS IN THE NEGOTIATION PROGRAM
- POTENTIAL COMMERCIAL CONTRACT IMPLICATIONS
- POTENTIAL LIABILITY ASSOCIATED WITH SECONDARY MANUFACTURERS’ COMPLIANCE
- NO MEDICAID DRUG REBATE PROGRAM PARTICIPATION → NO PART D INFLATION REBATE REQUIREMENT

POTENTIAL IMPACT TO PBM & PAYOR FEES IN 2023?
- NO DISCOUNT SAFE HARBOR PROTECTION
- ONLY PROTECTS FLAT FEES PAID TO PBMS FOR MANUFACTURER SERVICES (NOT FORMULARY)
- PBM LEGISLATION MOVING THROUGH CONGRESS

FURTHER CONTEXT FOR NEGOTIATION PROGRAM

POLITICAL
- MULTIPLE INTERCEDING CONGRESSIONAL & PRESIDENTIAL ELECTION CYCLES

JUDICIAL
- LEGAL CHALLENGE LIKELY AFTER SEP 1, 2023; POTENTIAL FOR DELAY

REGULATORY
- EVOLVING CMS GUIDANCE + IMPLEMENTATION RECORD
- PBMS MIGHT IMPACT PRICING BY 2032

PRACTICAL
- ONLY 20 DRUGS/YEAR ENTER THE PROGRAM
- INNOVATION STREAMLINING PRODUCTION & DISTRIBUTION COSTS, REVENUE
- POTENTIAL FOR COMPETITION?
- ROI CLIFF – IMPACT ON PRODUCT DEVELOPMENT & DEALS:
  - INDICATION & MOLECULE SEQUENCING
  - LAUNCH SEQUENCING
  - LICENSING FEES/ROYALTIES – RAMP DOWNS?
  - ASSET VALUATION IMPACT FOR EXITS, IPOS, JV, COLLABS

PENALTIES
- FAILURE TO OFFER MFP / PRIMARY MANUFACTURER MONITORING
- EXCISE TAX
- PROVIDING FALSE INFO
- VIOLATING NEGOTIATION AGREEMENT - $1M/DAY

PART D BENEFIT REDESIGN (EFF. JAN. 1, 2025)

<table>
<thead>
<tr>
<th>PHASE</th>
<th>CURRENT PART D BENEFIT</th>
<th>REDESIGNED PART D BENEFIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>INITIAL COVERAGE</td>
<td>ENROLLEE PAY 25% OF COSTS UNTIL OUT-OF-POCKET (OOP) SPEND HITS $4,660 (PLAN SPEND &amp; COPAYS COUNT TOWARD OOP)</td>
<td>OOP SPEND CAPPED AT $2,000 10% MANUFACTURER DISCOUNT REQUIRED (COPAYS NOT PLAN SPEND) COUNTS TOWARDS OOP</td>
</tr>
<tr>
<td>COVERAGE GAP / DONUT HOLE</td>
<td>ENROLLEE PAYS FOR ALMOST ALL BRANDED DRUG COSTS UNTIL OOP SPEND HITS $7,400 (COVERAGE GAP DISCOUNT AGREEMENT REQUIRES MANUFACTURER TO PROVIDE 7% DISCOUNT)</td>
<td>ELIMINATED</td>
</tr>
<tr>
<td>PHASE</td>
<td>ENROLLEE PAYS 5% OF BRAND COSTS</td>
<td>ENROLLEE PAYS 50% 20% MANUFACTURER DISCOUNT REQUIRED</td>
</tr>
</tbody>
</table>

MATT WETZEL
PARTNER, LIFE SCIENCES REGULATORY & COMPLIANCE
WASHINGTON, DC
202-346-4208
MWETZEL@GOODWINLAW.COM
### Biologics Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020-12-01</td>
<td>Initial offer</td>
</tr>
<tr>
<td>2021-01-11</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-02-14</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-03-11</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-04-14</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-05-11</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-06-14</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-07-11</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-08-14</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-09-11</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-10-14</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-11-11</td>
<td>Alternative offers</td>
</tr>
<tr>
<td>2021-12-14</td>
<td>Alternative offers</td>
</tr>
</tbody>
</table>

**What Happens If a Drug Is Selected**

- **Small Molecule Drugs:**
  - Initial offer does not include any specific dates.
  - Alternative offers are announced 30 days in advance.
  - The date of the final offer is determined by the CMS.

- **Biologics:**
  - Initial offer includes specific dates.
  - Alternatives are announced 30 days in advance.
  - The date of the final offer is determined by the CMS.

**Potential Selection for Drug Price Inflation Reduction Act Placement**

- **Small Molecule Drugs:**
  - Initial offer does not include any specific dates.
  - Alternative offers are announced 30 days in advance.
  - The date of the final offer is determined by the CMS.

- **Biologics:**
  - Initial offer includes specific dates.
  - Alternatives are announced 30 days in advance.
  - The date of the final offer is determined by the CMS.