Update on Compound Drugs

Mark Shelby, RPh
Director of Pharmacy Performance, CVS Caremark
Speaker Information

• Mark A Shelby, RPh., is the Director of Pharmacy Performance for CVS Caremark. His responsibilities include overseeing the Concurrent Review, Medicare Part D compliance audits, LTC pharmacy, Compounding auditing for Caremark's retail, mail and specialty national networks. He has given presentations around the country on preparing for pharmacy audits.

• Mark has worked in pharmacies for over 20 years. Post pharmacy school graduation, Mark’s experience began in chain retail pharmacy, transitioned to Hospital pharmacy, next to pharmacy director of Home Infusion pharmacy and then he decided to return to school to complete a Managed Care Residency. Following graduation, he was a supervisor for a large mail order pharmacy while he was a staff pharmacist at a compounding pharmacy, then he became the pharmacy director for a LTAC hospital, next off to work for a health plan, then off to a PBM, then off to pharmacy director for a national LTC pharmacy company, and the finally back to his current role at Caremark. He is adjunct professor at two Schools of Pharmacy.

• Mark has a BS degree in Pharmacy and completed his Managed Care Residency from Samford. He is a member of the National Healthcare Anti-Fraud Association (NHCAA) and the National Association of Drug Diversion Investigators (NADDI).
Mark Shelby declares no conflicts of interest, real or apparent, and no financial interests in any company, product or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.
Objectives
Pharmacists & Technicians

At the conclusion of this program, the pharmacist will be able to:

• Describe current issues in pharmaceutical compounding
• Describe differences between 5.1 and D.0
• Recognize payer remediation opportunities
• Identify pricing irregularities (clinical need vs. profit)
Compounding update!

1. Why compounding?
2. 5.1 vs D.0
3. Payer Remediation
4. Profit vs clinical need
The Utilization of Compound Drugs is a Growing Concern

More than 30 million prescriptions are compounded in the U.S. each year.¹

They are not approved by the FDA; not required to undergo the same studies for clinical efficacy and safety.²

Gross costs per compounded claim increased nearly 1,700%.²

Average gross cost per 30-day script grew more than 10X over a three-year period³

Due to rising costs, safety concerns and aggressive campaigning by compounding pharmacies we are enhancing our drug management strategies.

¹ http://www.brownscompounding.com/about-us/faqs.html
² BOB Employer only. CVS Health Enterprise Analytics, April 2014, data from January 2011 through March 2014.
³ CVS Health Enterprise Analytics, April 2014, Data from January 2011 through March 2014. *FDA website.
Increased Visibility Due to Sharp Rise in Cost Over the Past Three Years

AVERAGE GROSS COST PER 30-DAY SCRIPT OF COMPOUND DRUGS

Compound trend is increasing for employers and health plans. Medicare and Medicaid trends remain relatively flat.

Only for two months of Q3.
Compound Spend by Pharmacy ZIP ($1,000 or more)
## Compound Drugs vs. Traditional Therapies: Cost and Safety Considerations

**HENRY, AGE 40, DIAGNOSED WITH FIBROMYALGIA**

<table>
<thead>
<tr>
<th>FDA APPROVED FOR PRESCRIBED USE</th>
<th>COMPOUND MEDICATION*</th>
<th>TRADITIONAL THERAPY*</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOCUMENTED EVIDENCE OF EFFICACY</th>
<th>COMPOUND MEDICATION*</th>
<th>TRADITIONAL THERAPY*</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOLLOWS STRINGENT QUALITY GUIDELINES TO HELP ENSURE SAFETY</th>
<th>COMPOUND MEDICATION*</th>
<th>TRADITIONAL THERAPY*</th>
</tr>
</thead>
<tbody>
<tr>
<td>May vary by state</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COST</th>
<th>COMPOUND MEDICATION*</th>
<th>TRADITIONAL THERAPY*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost for Henry: $63.99/month¹</td>
<td>Cost for Henry: $25/month²</td>
<td></td>
</tr>
<tr>
<td>Cost for plan: $10,594.17/month²</td>
<td>Gross cost for plan: $258/month²</td>
<td></td>
</tr>
</tbody>
</table>

An effective compound drug strategy would help direct members to more cost-effective treatment with proven health outcomes.

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1. CVS/caremark, illustrative example of typical claim cost. 2. AWP for Cymbalta; other FDA-approved therapies are available, including a generic option. Projections based on CVS/caremark data. Individual results will vary based on plan design, formulary status, demographic characteristics and other factors. Client-specific modeling available upon request.
Compounds?? No per PBMs

Mixing containers/package sizes of the same drug into one container
- IVIG
- Albumin (without additives)

Meds requiring reconstitution prior to dispensing
- Flavor to oral abx
- Amox susp
- Cubicin

Combination of legend &/or non-legend products with no medical purpose
- Vitamin plus herbal supplement
- Adding three legend drugs into one capsule

Combo of drugs which are not combined to make a final medication
- Kits

These are examples of items not reimbursed as compounds
## Level of Effort (LOE) NCPDP Values

<table>
<thead>
<tr>
<th>Value Suggested</th>
<th>Value Description (required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Level 1 (Lowest) = Straightforward: Service involves minimal diagnosis or treatment options, minimal amount or complexity of data considered, and minimal risk; AND/OR Requires 1 to 4 MINUTES of the pharmacist's/compounder's time.</td>
</tr>
<tr>
<td>12</td>
<td>Level 2 (Low Complexity) = Service involves limited diagnosis or treatment options, limited amount or complexity of data considered, and low risk; AND/OR Requires 5 to 14 MINUTES of the pharmacist's/compounder's time.</td>
</tr>
<tr>
<td>13</td>
<td>Level 3 (Moderate Complexity) = Service involves moderate diagnosis or treatment options, moderate amount or complexity of data considered, and moderate risk; AND/OR Requires 15 to 29 MINUTES of the pharmacist's/compounder's time.</td>
</tr>
<tr>
<td>14</td>
<td>Level 4 (High Complexity) = Service involves multiple diagnosis or treatment options, extensive amount or complexity of data considered, and high risk; AND/OR Requires 30 to 59 minutes of the pharmacist's/compounder's time.</td>
</tr>
<tr>
<td>15</td>
<td>Level 5 (Highest) = Comprehensive = Service involves extensive diagnosis or treatment options, exceptional amount or complexity of data considered, and very high risk; AND/OR Counseling or coordination of care dominated the encounter and requires equal to or greater than 60 minutes of the pharmacist's/compounder's time.</td>
</tr>
</tbody>
</table>
Compounding update!

1. Why compounding?
2. 5.1 vs D.0
3. Payer Remediation
4. Profit vs clinical need
Claim Adjudication – NCPDP standard is one-step adjudication rather than continual feedback loop

- Pharmacy submits claim for payment to PBM
- Does the patient have secondary insurance?
- PBM Adjudicates claim according to plan design
- Second PBM Adjudicates patient obligation
- Yes
- No
- Transaction Complete
- Patient pays copay and receives dispensing
Multi-Ingredient Compounds

Individual ingredients submitted and processed through benefit design plan edits (coverage, pricing, etc)

Each covered ingredient priced separately and totaled for claim cost

- Includes Level of Effort (LOE)
- Dispensing fees

Route of administration required

Final dosage form required

Single copay applies
NCPDP D.0 Multi-Ingredient Processing

Claim elements still required
• Compound indicator
• Final Ingredient Cost Claimed
• Final Product Quantity
• Usual and Customary (U&C)

New processing elements include
• Submission of NDC for each ingredient
• Submission of quantities for each ingredient
• Submission of ingredient cost for each ingredient
• Final Route of Administration – SNOMED value
• Final Product Dosage Form (450-EF)
• Level of Effort (LOE)
Walking a Prescription through Adjudication
**NCPDP 5.1 Standard: Single Ingredient Processing**

**Compound Worksheet - Insurance Billing (SIC)**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>NDC (5-4-2 format)</th>
<th>Quantity Used (Final Product(*))</th>
<th>Quantity Used</th>
<th>AWP Cost per Unit</th>
<th>Extended Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>diphenhydramine</td>
<td>00603-0823-54</td>
<td>30 ml</td>
<td>0.016/ml</td>
<td>0.48</td>
<td></td>
</tr>
<tr>
<td>maalox</td>
<td>00667-0220-71</td>
<td>200 ml</td>
<td>0.0228/ml</td>
<td>2.45</td>
<td></td>
</tr>
<tr>
<td>nystatin 500,000 unit oral</td>
<td>53409-0400-01</td>
<td>60 ml</td>
<td>0.0687/ml</td>
<td>3.94</td>
<td></td>
</tr>
<tr>
<td>kenalog</td>
<td>00033-0293-28</td>
<td>5 ml</td>
<td>0.634/ml</td>
<td>31.7</td>
<td></td>
</tr>
<tr>
<td>lidocaine</td>
<td>06043-0464-00</td>
<td>40 ml</td>
<td>0.142/ml</td>
<td>5.68</td>
<td></td>
</tr>
</tbody>
</table>

* If utilizing a different quantity in final product than in recipe (i.e. lost medication in process) indicate as such

- **COMPOUND INDICATOR**
- **NDC of highest priced, legend ingredient**
- **Total final product quantity**
- **Total combined cost of ingredients**

**COMPOUND WORKSHEET - INSURANCE BILLING (SIC)**

<table>
<thead>
<tr>
<th>Rx# 123456</th>
<th>Name of Compound (incl strength)</th>
<th>Miracle Mouthwash (nystatin/triamcinolone/diphenhydramine/maalox/lidocaine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt Name</td>
<td>John Doe</td>
<td>Total Quantity (final product, incl dosage form)</td>
</tr>
</tbody>
</table>

Ingredients (Active and In-Active)
De not include labor, time, equipment, supplies, etc.

**Combined cost of all ingredients**

- **Combined cost of compound**
  - Transmit as a compound
  - Enter as total quantity on claims transmission
  - Enter NDC of highest priced legend ingredient (NDC with highest dollar value in extended price)
  - Enter combined cost of compound as ingredient cost claimed
**COMPOUND WORKSHEET - INSURANCE BILLING (SIC)**

<table>
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<tr>
<th>Rx#</th>
<th>123456</th>
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<tbody>
<tr>
<td>Pt Name</td>
<td>John Doe</td>
</tr>
<tr>
<td>Name of Compound (incl strength)</td>
<td>Miracle Mouthwash (Nystatin, triamcinolone, diphenhydramine, malox, lidocaine)</td>
</tr>
<tr>
<td>Total Quantity (final product, incl dosage form)</td>
<td>380 ml</td>
</tr>
</tbody>
</table>

**Ingredients (Active and In-Active)**
Do not include labor, time, equipment, supplies, etc.

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<td>0.016/ml</td>
<td>0.48</td>
<td></td>
</tr>
<tr>
<td>maalox</td>
<td>00067-0202-71</td>
<td>200ml</td>
<td>0.01228/ml</td>
<td>2.46</td>
<td></td>
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<tr>
<td>nystatin 500,000 unit oral</td>
<td>003498-0400-51</td>
<td>60ml</td>
<td>0.6807/ml</td>
<td>40.84</td>
<td></td>
</tr>
<tr>
<td>kenalog</td>
<td>00003-0293-28</td>
<td>5ml</td>
<td>6.634/ml</td>
<td>33.17</td>
<td></td>
</tr>
<tr>
<td>lidocaine</td>
<td>60432-0464-00</td>
<td>40ml</td>
<td>0.142/ml</td>
<td>5.68</td>
<td></td>
</tr>
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</tr>
</tbody>
</table>

**Combined cost of all ingredients**

<table>
<thead>
<tr>
<th>LOE Designation</th>
<th>Combined cost of compound</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>$82.63</td>
</tr>
</tbody>
</table>

Add professional allowance $30.00

Combined cost of compound $112.63

---

**Apply Lesser of Logic:**
- ICC: $112.63
- U&C: $150.00
- Client Rate:
  - Med D: $382.18
  - AWP (0.6807) x QTY (380) x 1.5

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* If utilizing a different quantity in final product than in recipe (i.e. lost medication in process) indicate as such.
# Adjudication logic D.o

## Elements Utilized in Adjudication Review

<table>
<thead>
<tr>
<th>NDC #s</th>
<th>Drug Name</th>
<th>Qty Sub</th>
<th>AWP Cost/Unit</th>
<th>Submitted Ingredient Cost</th>
<th>MAC (AWPxQTY-X%)</th>
<th>SUBMITTED COST</th>
<th>MAC, AWP CLIENT, OR SUBMITTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>00603-0823-54</td>
<td>Q-Dryl (diphenhydramine)</td>
<td>30</td>
<td>0.01627</td>
<td>$0.25</td>
<td>$0.41</td>
<td>$0.25</td>
<td>$0.25</td>
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<tr>
<td>00067-0254-44</td>
<td>Maalox</td>
<td>200</td>
<td>0.01302</td>
<td>$3.00</td>
<td>$2.21</td>
<td>$3.00</td>
<td>$2.21</td>
</tr>
<tr>
<td>53489-0400-01</td>
<td>Nystatin 500,000</td>
<td>60</td>
<td>0.6807</td>
<td>$41.00</td>
<td>$28.66</td>
<td>$34.72</td>
<td>$41.00</td>
</tr>
<tr>
<td>00003-0293-28</td>
<td>Kenalog</td>
<td>5</td>
<td>7.41797</td>
<td>$38.00</td>
<td>$31.53</td>
<td>$38.00</td>
<td>$31.53</td>
</tr>
<tr>
<td>60432-0464-00</td>
<td>Lidoacaine</td>
<td>40</td>
<td>0.142</td>
<td>$7.00</td>
<td>$1.43</td>
<td>$4.83</td>
<td>$1.43</td>
</tr>
</tbody>
</table>

*based on 15% $64.08

---

#1 Determination of Final Allowable Ingredient Cost

TOTAL ALLOWABLE INGREDIENT COST $64.08

plus allowable Dispensing Fee $1.50

plus LOE Value Allowable Cost $30.00

TOTAL FINAL ALLOWABLE INGREDIENT COST $95.58

---

Final Price

Lesser of the following:

A. ALLOWABLE FINAL INGREDIENT COST $95.58

B. USUAL AND CUSTOMARY (U&C) $100.00

C. FINAL INGREDIENT COST CLAIMED $99.00

FINAL PRICE $95.58

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### Notes

- One item must be a covered ingredient
- Coverage determination is per ingredient
- DUR, MDL, RTS review ingredient and claim level – dependencies

Assumption – all covered items

Commercial – if any line rejects – SCC 08
**Claim Example**

### Participant Pay
- **Participant Copay:** 50.00
  - **Flat Copay:** 50.00
  - **Insurance:** 0.00
  - **Pharmacy:** 0.00
  - **Prescriber:** 0.00
  - **Initial Copay:** 0.00
  - **Gap Copay:** 0.00
  - **Catastrophic Copay:** 0.00

### Client Pay
- **Transaction Amt:** 11625.32
- **Participant Contribution:** 50.00
- **Other Payer Recognized:** 0.00

**Total Client Cost:** 11575.32
- **LICS Paid By Plan:** 0.00
- **SPAP/Integrator Paid Amt:** 0.00

### Miscellaneous
- **Applied to MOOP:** 50.00
- **Applied to TROP:** 0.00
- **Applied to MAB:** 0.00
- **DAW Diff (CLT):** 0.00
- **ECL Amt (CLT):** 0.00
- **Excess MOOP:** 0.00
- **HRA Remaining Balance:** 0.00

### Total Submitted:
- **13401.04**
- **If COB, PIA:** No
- **Paid at U & C:** No

### Adjudicated
- **Ingredient Cost:** 11594.42
- **Dispensing Fee:** 0.90
- **Level Of Effort Fee:** 30.00
- **Administration Fee:** 0.00
- **Sales Tax:** 0.00

**Total Adjudicated:** 11625.32

**Total Allowed:** 11625.32
**Total Excluded:** 1775.72

---

**Total Participant Cost:** 50.00

---

**Total Participant Cost:** 50.00
Compounding update!

1. Why compounding?
2. 5.1 vs D.0
3. Payer Remediation
4. Profit vs clinical need
Payer Remediation and Risks

• **Compound trends**
  • Unique claims per item – break down 1 Rx into several
  • Resveratrol - $40k per claim
  • Pain Patches
  • Compound Benefit strategy – opt program
  • Kits

• **Pharmacies**
  • Pharmacies using copay coupon program
  • Shipping without licensure
  • Non-compliant pharmacies
  • Circumvent Plan edits

• **Legal**
  • New state audit laws
Compounds are Contributing to Double-Digit Trend

PAYOR TREND

2014 TREND DRIVERS

• Specialty: New drugs, higher launch prices, increased utilization
• 86 new products launched in 2014; 50+ expected in 2015. No significant new generics
• Price increases for most drugs, including double-digit rise for brand-name drugs
• Top classes include Antiviral, Antidiabetics and Compounds.

Source: 2014 Enterprise Analytics as of Q314; excludes compounds due to client-specific strategies; Pipeline Services.
# Payer Remediation

## Network
- Compound credentialing
- Compound only Network
- Non-Compounding Network

## Benefit Design
- Prior Authorizations on all
- Prior Authorization with $ threshold
- Exclusion list
- Step Therapy

## Pharmacy Audit
- Adherence to Benefit Design
- Cut quantities
- Billing the actual products used
- Pharmacy standards – licensure, copay collection, law
- Pedigree information
## Payer Remediation

| New products                      | Wellness capsules  
Pain Patches  
Stability – BUD, Bioavailability  
Does it stay as final product? |
|-----------------------------------|-------------------|
| State / Federal Laws             | CMS – def of a covered drug  
Medicaid Regulations  
State Audit Laws                  |
| Pharmacy                         | Physician ownership – self referrals  
W2 sales force  
Coupon programs, package refunds  
Compliance to USP 795, pharmacy contracts |
Compounding update!

1. Why compounding?
2. 5.1 vs D.0
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4. Profit vs clinical need
<table>
<thead>
<tr>
<th></th>
<th>Code</th>
<th>Description</th>
<th>Unit Price</th>
<th>Total Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>52372085404</td>
<td>MORPHINE-POW-SULFATE</td>
<td>48.00</td>
<td>4432.56</td>
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<td>2</td>
<td>52372091210</td>
<td>GABAPENTIN-POW-</td>
<td>48.00</td>
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</tr>
<tr>
<td>3</td>
<td>52372088505</td>
<td>KETAMINE HCL-POW-</td>
<td>27.60</td>
<td>810.96</td>
</tr>
<tr>
<td>4</td>
<td>52372090110</td>
<td>DIPHENHYDRAM-POW-HCL</td>
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<td>38.68</td>
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<td>76.17</td>
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<tr>
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<td>7</td>
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<td>290.13</td>
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<td>8</td>
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<td>2216.28</td>
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<td>DIMETHYL-SOL-SULFOXID</td>
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<td>PCCA LIPODER-CRE-BASE</td>
<td>229.680</td>
<td>385.63</td>
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### Claim Example

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<tr>
<th>Seq. #</th>
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<th>Dispensed Drug</th>
<th>Dispensed Quantity</th>
<th>Mod D</th>
<th>Ingredient Cost</th>
<th>Status</th>
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<td>FLUTICASONE-POW-PROPIONA</td>
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<td>3</td>
<td>51927126900</td>
<td>UREA-POW-</td>
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<td>ITRACONAZOLE-POW-</td>
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<td>5</td>
<td>62991133401</td>
<td>PEG 300-LIQ-</td>
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<td>1.08</td>
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<td>SPIRA-WASH-GEL-RASF</td>
<td>86.400</td>
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**Tail Man:** MUP5%/FLU1%/ITR5%/URE40% SPIRA-WASH GEL  
**Flavor:**  
**Description:**  
**Quantity made:** 1000 GM  
**Batch yield:** 1,000,000  
**Date made:** 07/24/2014  
**Lot number:** 07242014@4  
**Beyond use date:** January 10, 2015  
**PCCA ID:**  
**Schedule:**  
**Active:** Yes  
**Formula ID:** 340  
**Log ID:** 1009

### Pricing Calculations from the Log

- **Estimated price** as of 02/19/2014: $58,036.30
- **Ingredient cost**: $3,977.22
- **Device cost**: $0.00
- **Time cost**: $0.00

**Profit**: $54,238.08

**Time to make**: 0
### Pricing of prescriptions

**COST VS AWP**

**Compound type: Pain management**

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>NDC</th>
<th>QUANTITY</th>
<th>UM</th>
<th>PRICE</th>
<th>COST</th>
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<td>FLURBIPROFEN POWDER</td>
<td>38779-0362-09</td>
<td>60.000</td>
<td>GM</td>
<td>2319.90</td>
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<td>Lot#: N/A, DEA: 0, Expiry: 4/12/2016, Manufacturer: MEDISCA INC.</td>
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<td>BACLOFEN POWDER</td>
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<td>LIDOCAINE POWDER</td>
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<td>PROPYLENE GLYCOL LIQUID</td>
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</table>
Copayment Waiver is Evolving

- Pharmacies are characterizing programs that waive a copayment as a Coordination of Benefits or Pharmaceutical Manufacturer Coupon
- Only means to detect is through member sampling, and audits of copayment evidence
- HHS OIG highlighted in a recent report that a PBM cannot see activities that occur post-adjudication. These Copayment Waiver schemes are acting on this issue to take advantage
Questions?