Arkansas Medicaid Evidence-based Prescription Drug Program

Submitting Supplemental Rebate Offers

Pamela Ford, P.D., MBA
pamela.ford@arkansas.gov

Arkansas Department of Health and Human Services
Finding the Info

www.medicaid.state.ar.us

Arkansas Department of Health and Human Services
Prescription Drug Information

Provider information

Current providers

To verify patient eligibility and benefits, file claims, check a previously filed claim's status, update provider demographic information or utilize other Medicaid applications, type your provider ID and tax ID/SSN and click Submit.

Log on
Provider ID: [ ] Tax ID/SSN: [ ]
Evidence-Based Prescription Drug Program

Prescription drug information

If you have pharmacy claim or prescription drug prior authorization concerns, please call the Prescription Drug PA Help Desk:
In-state toll free
(800) 707-3854
Local and out-of-state
(501) 374-8609 x 600

The documents listed in the tables below are in Microsoft Word format (.doc or .rtf), Microsoft Excel format (.xls), or portable document format (.pdf). When you click the link, the document opens in a new window. To return to this page, close the window.

If you click a link but the document doesn’t open, download Microsoft Word Viewer, download Microsoft Excel Viewer, or download Adobe Acrobat Reader free so you can view and print the documents.

Alternate drugs that do not require prior authorization through the VRS nor Clinical Edits
Capped upper limits
Cough and cold list
Covered labels
Evidence-Based Prescription Drug Program
Exclusions from coverage
Generic upper limits
Medicare Part D excluded—allowed by Arkansas Medicaid
MedWatch forms, and information

Arkansas Department of Health and Human Services
Evidence-Based Prescription Drug Program

Welcome to Arkansas Medicaid - Microsoft Internet Explorer

View the Official Notice regarding the Evidence-Based Preferred Drug List.

<table>
<thead>
<tr>
<th>Program overview and PDL list</th>
<th>File name</th>
<th>File size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred and Non-Preferred Drug List</td>
<td>PDL.xls</td>
<td>217k</td>
</tr>
<tr>
<td>Program Overview for Arkansas Medicaid Evidence-based Prescription Drug Program</td>
<td>ProgramOverview.pdf</td>
<td>96k</td>
</tr>
<tr>
<td>PDL Clinical Criteria Overview</td>
<td>PDLCriteria.doc</td>
<td>291k</td>
</tr>
</tbody>
</table>

Provider notifications

<table>
<thead>
<tr>
<th>Provider notifications</th>
<th>File name</th>
<th>File size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Notification on 5-HT3 Receptor Antagonists (Newer Antianxiety Agents) -- October 10, 2006</td>
<td>pdfAntianx.pdf</td>
<td>155k</td>
</tr>
<tr>
<td>Provider Notification on Anticholinergic Agents to Treat Overactive Bladder Syndrome -- June 16, 2006</td>
<td>pdfOAB.pdf</td>
<td>156k</td>
</tr>
<tr>
<td>Provider Notification on Inhaled Corticosteroids, Metered Dose Inhalers and Dry Powder Inhalers -- May 12, 2006</td>
<td>pdfICS.pdf</td>
<td>154k</td>
</tr>
<tr>
<td>Provider Notification on Change to Non-Preferred status for Nuvance -- July 1, 2006</td>
<td>pdfNuvance.pdf</td>
<td>143k</td>
</tr>
<tr>
<td>Provider Notification on Targeted Immune Modulators -- March 7, 2006</td>
<td>pdfTmds2.pdf</td>
<td>142k</td>
</tr>
<tr>
<td>Provider Notification on Newer Sedative Hypnotic drugs, except Zolpidem -- March 7, 2006</td>
<td>pdfSedhypnotics.pdf</td>
<td>155k</td>
</tr>
<tr>
<td>Provider Notification on Postmenopausal systemic Estrogens -- February 14, 2006</td>
<td>pdfEstrogen.pdf</td>
<td>154k</td>
</tr>
<tr>
<td>Provider Notification on Skeletal Muscle Relaxants --</td>
<td>pdfSkMusRel.pdf</td>
<td>157k</td>
</tr>
</tbody>
</table>

Arkansas Department of Health and Human Services
Manufacturer Information

Welcome to Arkansas Medicaid - Microsoft Internet Explorer

Provider Notification on Triptan Agents Drug Class – December 8, 2006
Provider Notification on Long-Acting Narcotic Agonist Analgesics Drug Class – October 26, 2005
Guidelines for Opioid Dosage Conversion Ratios
Provider Notification on Angiotension Converting Enzyme Inhibitors – September 19, 2005
Provider Notification on Beta Adrenergic Blockers Drug Class – August 5, 2005
Provider Notification on Calcium Channel Blocker Drug Class – July 12, 2005
Provider Notification on HMG-CoA Reductase Inhibitors Drug Class – June 9, 2005
Provider Notification on PPI Drug Class – March 18, 2005
Provider Notification on 2nd Generation Antihistamines – January 25, 2005

Manufacturer information

Notice to Manufacturers for the Nasal Corticosteroid drug class
Notice to Manufacturers for data change of review for Anti-Diabetic Agents
Arkansas Supplemental Rebate Agreement Template
Supplemental Rebate Offer Envelope Labeling Requirements

Arkansas Department of Health and Human Services
As announced at the October 27, 2014 Arkansas Drug Utilization Review Board meeting, drug manufacturers may submit offers for supplemental rebates to Arkansas Department of Health and Human Services Division of Medical Services Medicaid Pharmacy. The Arkansas Medicaid Drug Review Committee (DMRC) is preparing for the evidence-based review of the drug class (a). The Federal Centers for Medicare and Medicaid Services (CMS) approved Arkansas Medicaid’s State Plan Amendment for supplemental rebates in November 2004. CMS has also approved the contract template for supplemental rebates.

The procedures set forth in this letter are mandatory and must be followed in order to submit a supplemental rebate offer. ADMHS/DMC will reject any rebate offer which does not conform to the requirements herein. ADMHS/DMC will deem any bid non-conforming which contains additions or deletions to the Supplemental Rebate Agreement or any attachments thereto, other than those calculations necessary to complete the attachments including cost adjustments in anticipation of inflation. All non-conforming bids will be rejected by the ADMHS/DMC.

1. Drug manufacturers must comply with the Evidence-Based Preferred Drug List policy and the contract template and the Attachments, to submit offers. All offers are to be calculated at net cost, as defined in Attachment B of the contract template. Manufacturers shall include on Attachment A each of the following terms used to calculate the Part B drug reimbursement rate, the final CMS rebate per unit of covered product, and the State Supplemental Rebate offer per unit of covered product.

2. Government agencies are directed to use National Drug Codes (NDCs) in an electronic format. For example, Centers for Medicare & Medicaid...

Arkansas Department of Health and Human Services
Common Pitfalls

Non-Conforming Bids:

- Late submission
- Missing Procurement ID
- Net Cost Different for Same Strength/Diff. Pkg Sizes
- Changes to Contract Language
- Net Cost Offer
- Signed Contract Not Included
Late Submission

- Supplemental rebate offers for specific drugs must be received no later than one week before the scheduled Drug Review Committee (DRC) meeting during which the review for that particular drug class will begin with the public comments. *Public comments for the** DRUG CLASS NAME **will be heard on** DRC MEETING DATE.

- Drug manufacturers interested in submitting offers for supplemental rebates for **DRUG CLASS NAME** must submit offers no later than 4:30 p.m. Central Standard Time (CST) on **CLOSING DATE** to:

- **No offers will be accepted after that time.**
Can I FAX to Meet the Deadline?

☐ FAX submission is not acceptable and any supplemental rebate contract offers sent by fax to DHHS will be rejected.

☐ The supplemental rebate contract offer may be hand delivered or sent first class mail.
Mailing Address

Ray Stafford, Procurement Supervisor
Attention: State Supplemental Drug Rebate Procurement ID xxx XXX
DO NOT OPEN
Slot W345, 700 Main Street
Little Rock, AR 72201
What is the Procurement ID??

- Why is the Procurement ID important?

- What happens to envelopes without identifying information?
Mailing Address

Ray Stafford, Procurement Supervisor
Attention: State Supplemental Drug Rebate *Procurement ID xxx XXX*
DO NOT OPEN
Slot W345, 700 Main Street
Little Rock, AR 72201
The NDC Number

- The National Drug Code (NDC) is a unique, three-segment number, which is a universal product identifier for human drugs.
- The first segment, the labeler code, is assigned by the FDA.
- The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm.
- The third segment, the package code, identifies package sizes and types. Both the product and package codes are assigned by the firm.
- The FDA’s standard for the NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.
The “9-Digit” NDC

- Government agencies use the HIPAA standard of an 11 digit NDC. For example, Centers for Medicare & Medicaid Services (CMS) displays the labeler code as 5 digits with leading zeros; the product code as 4 digits with leading zeros; the package code as 2 digits with leading zeros, using a 5-4-2 format.

- The Net Cost offer shall be stated as a price per unit based on the NDC labeler and product codes, commonly referred to as “the 9-digit NDC” without the package code digits.
Thou Shalt Not … Change the Contract Language

- ADHHS/DMS will deem any bid non-conforming which contains additions or deletions to the Supplemental Rebate Agreement or any attachments.

- Changes made to the rebate agreement must be submitted by the State to CMS for review and will require approval of a new state plan amendment.
The Net Cost Offer

- All offers are to be calculated as the final net cost to the State.

- When calculating Net Cost, the current ingredient reimbursement for brand product is AWP – 14%; current ingredient reimbursement for generic product is AWP – 20%.
The Net Cost Offer

- The final Net Cost to the State shall be calculated using the Ingredient Reimbursement Rate (IRR) less the final CMS rebate per unit of covered product (Final CMS Rebate) and the State Supplemental Rebate offer per unit of covered product (SSR).

- Show the math—why is this important?
  \[
  \text{Net Cost} = \text{IRR} - \text{Final CMS Rebate} - \text{SSR}
  \]
SHOW THE MATH!

**Drug A, XX mg**

3.5122  AWP

-  **14%**

3.020492  Reimbursement Rate

-0.8806  CMS Rebate 1Q06

2.139892  net cost

-  **5057**  Supplemental Rebate

1.634192  Final Net Cost

Arkansas Department of Health and Human Services
Looking at the Whole Picture

- Recommendations by the DRC
- Compare the offered Net Cost to the current Net Costs.
- The most commonly prescribed strengths in relation to the offered final Net Cost.
- Compare frequency of dosing and equivalent dosing if available.
- Comparing offers for 1 of 1, 1 of 2, and 1 of 3.
- Potential for abuse, availability.
Example of AR Medicaid Preferred Drug Market Shift

HMG-CoA REDUCTASE INHIBITORS

# of Rx's

Preferred Rx's
Non-Preferred Rx's

Reporting Period

Arkansas Department of Health and Human Services
Example of AR Medicaid Preferred Drug Market Shift

PROTON PUMP INHIBITORS

# of Rx’s

- Preferred Rx’s
- Non-Preferred Rx’s

Reporting Period

Arkansas Department of Health and Human Services
Example of AR Medicaid Preferred Drug Market Shift

Arkansas Department of Health and Human Services
Example of AR Medicaid Preferred Drug Market Shift

LONG ACTING OPIOIDS

<table>
<thead>
<tr>
<th>Reporting Period</th>
<th># of Rx's</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEPTEMBER</td>
<td>2,000</td>
</tr>
<tr>
<td>OCTOBER</td>
<td>1,500</td>
</tr>
<tr>
<td>10/26/05 PDL IMPLEMENTED</td>
<td>1,000</td>
</tr>
<tr>
<td>NOVEMBER</td>
<td>500</td>
</tr>
<tr>
<td>DECEMBER</td>
<td>0</td>
</tr>
<tr>
<td>JANUARY</td>
<td>0</td>
</tr>
<tr>
<td>FEBRUARY</td>
<td>0</td>
</tr>
<tr>
<td>MARCH</td>
<td>0</td>
</tr>
<tr>
<td>APRIL</td>
<td>0</td>
</tr>
<tr>
<td>MAY</td>
<td>0</td>
</tr>
<tr>
<td>JUNE</td>
<td>0</td>
</tr>
</tbody>
</table>

Prefered Rx's vs Non-Preferred Rx's
Example of AR Medicaid Preferred Drug Market Shift

ANTIHISTAMINE - NONSEDATING

# of Rx's

<table>
<thead>
<tr>
<th></th>
<th>Preferred Rx's</th>
<th>Non-Preferred Rx's</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MARCH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APRIL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JUNE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JULY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUGUST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEPTEMBER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OCTOBER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOVEMBER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DECEMBER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JANUARY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEB</td>
<td>Preferred Rx's</td>
<td>Non-Preferred Rx's</td>
</tr>
<tr>
<td>MARCH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APRIL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JUNE</td>
<td>Preferred Rx's</td>
<td>Non-Preferred Rx's</td>
</tr>
</tbody>
</table>

Reporting Period

Arkansas Department of Health and Human Services
Include a Signed Contract

- An original executed copy of the Arkansas Supplemental Rebate Agreement must be submitted with the supplemental rebate offer.
What to do about a New Strength of Preferred Agent

- If after selection of a preferred agent(s), the manufacturer develops a new strength(s) of the preferred agent(s), the new strength(s) may be covered as a preferred agent on the same basis as the original strength(s) so long as:
  1. the manufacturer notifies Arkansas DHHS on or before the date of the new agent(s) availability for Medicaid coverage, and
  2. the manufacturer states that it will provide a rebate for the new strength equivalent to the same percentage of the Average Wholesale Price (AWP) as was used in the previously accepted rebates for that agent.
- If the manufacturer does not provide a rebate on the new strength, the new strength shall not be covered as a preferred agent.
“Obsolete” NDC
“Replacement” NDC

- If a Preferred Agent is identified as an “Obsolete” NDC, we will apply the previously accepted offer to the “Replacement” NDC identified in the system.
Manufacturer Appeal Process

Mail that is marked with a Procurement Identification and received by the bid deadline and identified as a drug rebate bid will be routed to a screener designated by the Director of the Division of Medical Services (DMS) to determine, using the criteria set forth in the bid letter, whether the bid conforms to the bid request. This screener shall have no input in any drug rebate decision.

2. Within three business days of identifying a bid that does not conform to all bid requirements, a dated written notice of the nonconformity will be mailed via regular mail to the tendering party.
Manufacturer Appeal Process

☐ Who is the “screener”

- The DMS Director or his reviewing designee.
- This designee shall have no input in any drug rebate decisions--this person is not on the Cost Committee.
3. The party that tendered a nonconforming drug rebate bid may:

a) **Submit a written exception to the DMS Director or his reviewing designee in accordance with the following:**

   i. The written exception shall be received by the DMS Director or a person designated to review bid nonconformity decisions within seven (7) calendar days after the date of the DMS notice to the tendering party that the bid is non-conforming. This reviewer shall have no input into the original determination of nonconformity or any drug rebate decision;

   ii. The written exception shall state, and provide any supporting documentation to establish, how and why the bid conformed to all applicable bid requirements;
Manufacturer Appeal Process

(b) Submit a bid amendment to correct the nonconformity to the DMS Director or his reviewing designee in accordance with the following. This designee shall have no input into the original determination of nonconformity or serve on the cost committee.

(i) Each bid amendment shall be received by the DMS Director or the person designated to decide bid conformity within seven (7) calendar days after the date of the DMS notice to the tendering party that the bid is non-conforming.

(ii) Each bid amendment will replace and supplant all bid contents that were identified as nonconforming. If the nonconformity resulted from an omission, the bid amendment will add to the previously submitted bid contents.
iii. The tendering party *may not appeal* either failure to supply a Procurement Identification or failure to timely submit a bid by the bid deadline per the criteria set forth in the bid letter.
(iv) Only one bid amendment per bid submission is permitted. Upon receiving the amendment the deciding official will determine if the bid as amended conforms to the bid request. If the bid as amended conforms to the bid request the bidder shall be notified and the bid as amended considered on an equal basis with other bids.

(v) If the bid as amended is determined to be nonconforming, the tendering party may follow the procedure set forth in Section 3 (a).
Manufacturer Appeal Process

- Who is the ‘reviewer’ (reviewing the ‘exception’ or the ‘amendment’)?
  - The DMS Director or his reviewing designee.
  - This designee shall have no input into the original determination of nonconformity or serve on the cost committee for any drug rebate decisions.
Common Pitfalls

1. Late submission—cannot appeal
2. Missing Procurement ID—cannot appeal

- Net Cost Different for Same Strength/Diff. Pkg Sizes
- Changes to Contract Language
- Net Cost Offer
- Signed Contract Not Included