Medicaid Pharmacy Reimbursement Overview

June 13, 2007

Jennifer Kowalski
Avalere Health LLC
Medicaid Pharmacy Reimbursement Overview

- States set their own drug reimbursement policies; payments are required to approximate drug acquisition costs plus a reasonable dispensing fee.

- Most states currently use one of two metrics to estimate acquisition costs:
  
  - **Average Wholesale Price (AWP)** – specified %
  
  - **Wholesale Acquisition Cost (WAC)** + specified %

- Federal and state cost containment programs also limit reimbursement:

  - **Federal Upper Limit (FUL)** – applies in aggregate to multi-source drugs
  
  - **Maximum Allowable Cost (MAC)** – state-set limits for select drugs
Medicaid Rebates and Average Manufacturer’s Price

- Under the Medicaid Drug Rebate Program, manufacturers pay rebates to states for the drugs dispensed to Medicaid beneficiaries equal to:
  - 15.1% **Average Manufacturer’s Price (AMP)**
  - Difference between AMP and **Best Price**

- AMP was created solely for the purposes of the rebate program to approximate acquisition costs to the retail class of trade
  - Drugs in the Medicaid rebate program – brand or generic – have an AMP

- Deficit Reduction Act (DRA) of 2005 expanded the use of AMP and required new clarity of its definition
CMS Issued AMP Rule in December

- Implements provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program
- Adds to existing regulations and guidance on Medicaid best price
- Clarifies existing guidance on collection of Medicaid rebates for physician-administered drugs
- Released by CMS December 15, 2006; publication in Federal Register December 22, 2006
- Comments due February 20, 2007
- Final Rule expected July 1, 2007?
## Proposed AMP Rule

<table>
<thead>
<tr>
<th>Provision</th>
<th>Past Medicaid Policy</th>
<th>New Medicaid Policy</th>
<th>Statutory Implementation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Redefinition of AMP</strong></td>
<td>AMP was not well defined, creating variation in AMP calculations across manufacturers</td>
<td>AMP will be defined clearly as to the inclusion/exclusion of discounts to certain entities</td>
<td>July 2007</td>
</tr>
<tr>
<td></td>
<td>Prompt pay discounts included in AMP</td>
<td>Prompt pay discounts excluded</td>
<td></td>
</tr>
<tr>
<td><strong>Publication of AMPs</strong></td>
<td>AMPs confidential; no sharing with states and no public posting</td>
<td>AMPs shared with states and published publicly monthly</td>
<td>July 2006 – AMPs shared with states</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Public posting delayed</td>
<td></td>
</tr>
<tr>
<td><strong>Federal Upper Limit (FUL) for multiple source drugs</strong></td>
<td>150% AWP for drugs with three+ therapeutic equivalents</td>
<td>250% AMP for drugs with two+ therapeutic equivalents</td>
<td>January 2007</td>
</tr>
<tr>
<td><strong>Nominal Price Definition</strong></td>
<td>Nominal price defined as less than 10% of each quarterly AMP, regardless of the purchaser of the product</td>
<td>Limits definition of nominal sales eligible for AMP and best price exemptions</td>
<td>January 2007</td>
</tr>
</tbody>
</table>
# AMP: Proposed Included and Excluded Prices & Discounts

## Included in Calculation: Prices/Sales and Discounts

- Wholesalers\(^\text{1}\)
- Retail pharmacies
- PBMs
- Hospitals, where the drug is used in the outpatient pharmacy
- Sales directly to patients from the mfr.
- Mail order pharmacies
- Outpatient clinics
- Manufacturers who act as wholesalers and do not repackage/relabel under purchaser’s NDC
- Any other price concessions to the retail class of trade
- Manufacturer coupons redeemed by entity other than consumer
- **Medicare Part D plans**
- Authorized generic drugs
- SCHIP
- **SPAPs**
- Medicaid sales (excl. rebates)

*Except as specifically excluded at right.*

## Excluded from Calculation: Prices/Sales and Discounts

- IHS, VA, qualifying state home, DoD, PHS, 340B entities, FSS, depot prices including Tricare, or other approved federal agency.
- Rebates or supplemental rebates to Medicaid agencies
- Hospitals, where the drug is used in the inpatient setting
- Nominal prices to specified entities
- Manufacturer coupons redeemed by a consumer
- HMOs or MCOs
- LTC facilities including nursing home pharmacies
- Free goods not contingent upon any purchase requirement
- Bona fide service fees
- Wholesalers where the drug is distributed to the non-retail class of trade
- Wholesalers where the drug is relabeled under the wholesalers’ NDC number
- **Customary prompt pay discounts**
- Returned goods

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Note: Items that are treated differently for AMP and best price are bolded and underlined.

\(^1\) Except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities.
2007 AMP Reporting Timeline

Monthly AMP Reporting Starts*

States begin requiring use of NDCs when billing Medicaid for physician administered drugs (including hospital outpatient department)

Comments due on Proposed AMP Rule

Q4 2006 Best Price, Prompt Pay**, and Quarterly AMP Submissions due to CMS

Q1 2007 Best Price, Prompt Pay, and Quarterly AMP Submissions due to CMS

AMP Rule to be finalized

Estimated that AMP Data will be released publicly

Q2 2007 Best Price, Prompt Pay, and Quarterly AMP Submissions due to CMS

Q3 2007 Best Price, Prompt Pay, and Quarterly AMP Submissions due to CMS

Jan 1, 2007

Feb 1, 2007

Feb 20, 2007

May 1, 2007

Jul 1, 2007

Aug 1, 2007

Nov 1, 2007

Monthly AMP submissions are due 30 days after month end.

*The AMP data to be submitted to CMS on a monthly basis has not been specified by CMS yet (i.e., whether manufacturers utilize their existing definition of AMP or the proposed definition).

**It is assumed that the quarterly prompt pay submission requirements pertains to Q4 2006 prompt pay data.
**AMP – What’s Required?**

<table>
<thead>
<tr>
<th>Required by DRA</th>
<th>Decision of States and Other Payers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Upper Limit set at 250% AMP, in the aggregate, for multi-source drugs with two or more therapeutic equivalents</td>
<td>States may continue to set reimbursement as they choose – at, above, or below 250% AMP – as long as reimbursement for these drugs, in the aggregate, does not exceed the FUL</td>
</tr>
<tr>
<td>Monthly reporting of AMP by manufacturers to CMS</td>
<td>States may choose to use AMP and/or RSP in their reimbursement formulas; states may continue to use AWP or WAC</td>
</tr>
<tr>
<td>CMS, in turn, reports AMP monthly &amp; provides retail sales price (RSP) to states</td>
<td>States may choose to use AMP and/or RSP to determine state MACs; states may elect to make no changes</td>
</tr>
<tr>
<td>Public posting of AMP by CMS</td>
<td>Other payers may choose to use AMP as the basis for their outpatient drug reimbursement metrics</td>
</tr>
</tbody>
</table>
AMP: Implications and Opportunities

June 13, 2007

Lauren Barnes
Avalere Health LLC
AMP Reform Is Here, But Where is It Going?

**Phase 1: OBRA '90**
- Medicaid Drug Payment Reform

**Phase 2: Rising Drug Costs**
- Expanding retail class of trade
- State focus on cost containment

**Phase 3: Critical Juncture**
- DRA redefines and publishes AMP

**Phase 4: Looking Ahead**

**Time**
- 1990–1991
- 1992–2002
- 2003–Present
AMP: Perspective of Manufacturers and Pharmacies

- **Tight**
  - Fewer discounts are included
  - Increased rebate liability for manufacturers
  - Increased reimbursement for pharmacies

- **Broad**
  - More discounts are included
  - Decreased rebate liability for manufacturers
  - Decreased reimbursement for pharmacies
Over 1300 Comments Were Submitted on the AMP Proposed Rule

<table>
<thead>
<tr>
<th>Commentator Type*</th>
<th>Number of Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturers</td>
<td>33</td>
</tr>
<tr>
<td>Wholesalers/Distributors</td>
<td>5</td>
</tr>
<tr>
<td>PBMs</td>
<td>3</td>
</tr>
<tr>
<td>Hospitals</td>
<td>49</td>
</tr>
<tr>
<td>Trade Groups</td>
<td>6</td>
</tr>
<tr>
<td>Law Firms</td>
<td>5</td>
</tr>
<tr>
<td>Pharmacy Associations</td>
<td>29</td>
</tr>
<tr>
<td>Pharmacy Chains</td>
<td>16</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>~1158</td>
</tr>
</tbody>
</table>

*Does not represent all commenter types.
## Major Themes Among Commentators

<table>
<thead>
<tr>
<th>Proposed Rule</th>
<th># of Commentators</th>
<th>Examples of Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclude Discounts to Long Term Care Pharmacies</td>
<td>Yes: 42, No: 2, Other: 1</td>
<td>“Many LTC residents are dual eligibles. It seems inconsistent to exclude LTC sales while at the same time proposing to include sales to Part D.”</td>
</tr>
<tr>
<td>Include Discounts to Mail-order Pharmacies</td>
<td>Yes: 10, No: 324, Other: 1</td>
<td>“Retail pharmacy class of trade should be defined consistently with…Medicare Part D, and should exclude all non-retail pharmacies, such as mail order pharmacies, since these…not only serve different populations…, but also operate under very different business models.”</td>
</tr>
<tr>
<td>Include Discounts to PBMs</td>
<td>Yes: 16, No: 324, Other: 4</td>
<td>“…It is difficult for manufacturers to disaggregate PBM terms. Perhaps the most practical and consistent approach would be one …that all PBM rebates and discounts as well as those to health plans described above should be included in AMP. Without such specificity, the ambiguity CMS is attempting to eliminate would remain in place…”</td>
</tr>
<tr>
<td>Include Discounts on Hospital Outpatient Drugs</td>
<td>Yes: 0, No: 29, Other: 5</td>
<td>“Sales to hospitals and outpatient clinics should be omitted given that these entities do not fall within the definition of a traditional retail pharmacy, even if these drugs are dispensed at outpatient clinics.”</td>
</tr>
<tr>
<td>Maintains Current List of Safety Net Providers for 340B Nominal Pricing</td>
<td>Yes: 0, No: 36, Other: 0</td>
<td>“We urge CMS to exercise their authority, such as through adoption of the IOM definition of safety net providers…”</td>
</tr>
</tbody>
</table>
Congress Has Engaged in the AMP Debate

Six Members of Congress submitted comments on the AMP rule

Major Themes

- CMS should expand the list of safety net providers eligible for nominal pricing
- Including discounts made available to mail order pharmacies and PBMs does not reflect the prices paid by retail pharmacies
- Delay release of current AMP data for use by states and the public if they are not consistently calculated by manufacturers, or if the method by which they will be calculated will change once the regulation’s definition of AMP is made final

Unique Comments

- CMS did not adequately contemplate the impact of the proposed rule on small retail pharmacies and evaluate alternatives to the proposed rule to minimize the economic impact on small entities to the extent it is obligated to do so pursuant to the Regulatory Flexibility Act

Grassley sent a letter to CMS on May 14th urging for the removal of PBM discounts/rebates from AMP so that AMP would more accurately represent pharmacy acquisition costs.
AMP Will Differ From ASP in Regard to Implementation for Reimbursement

**ASP:**
- Mandated as a reimbursement index
- Reimbursement rate set nationally at ASP + 6%
- No local discretion as to the reimbursement rate or timing
- Physician administration fees increased nationally

**AMP:**
- Not mandated as a reimbursement index
- No reference to reimbursement rate (AMP + X%)
- State by state variation in use of AMP and reimbursement rate
- Dispensing fees increased per state discretion
Summary of States’ Plans to Use AMP for Medicaid Pharmacy Reimbursement

47 States responded

- 39 States have not decided whether to use AMP
  - 14 States will consider using AMP for estimated acquisition costs
  - 4 States will consider using AMP to establish state MACs
  - 21 States don’t know/did not indicate they will consider using AMP data
- 4 States planning to use AMP for reimbursement have not implemented
- 1 State planning to use AMP to help determine MACs
- 1 State will use AMP for estimated acquisition costs
- 1 State will compare MACs to AMP-based FULs
- 3 States not planning to use AMP

In addition, 16 of the 47 States Were Unaware That CMS Is Collecting and Disseminating RSP Data Until Receiving the Survey.

Conclusions

- AMP final rule may be delayed
  - However, some at CMS and within Congress have predicted a timely release
- Congress and pharmacy community urging caution in using AMP for reimbursement
- First Databank’s discontinuation of AWP in 2008 could accelerate AMP movement
- Still unclear as to how states will react individually:
  - AMP + X%
  - Dispensing fee increases: generic vs. brand
- What will private payers and Medicare Part D plans do?