Welcome

Larry Hogan, Governor
Boyd Rutherford, Lt. Governor
Dennis Schrader, Secretary
Pharmacy Stakeholder Meeting

Athos Alexandrou, MBA
Director
Maryland Medicaid Pharmacy Program

January 9, 2017
WELCOME

- Opening Remarks
- Introductions
Contact Names
Darold Barnes, RPh (Pharmacy Manager)
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AGENDA

- Overview of Covered Outpatient Drugs Final Rule (CMS-2345-FC)
  - Federal Upper Limit (FUL)
  - Actual Acquisition Cost (AAC)
  - National Average Drug Acquisition Cost (NADAC)
  - State Actual Acquisition Cost (SAAC)
  - Professional Dispensing Fee
- Ingredient Cost Survey
- Proposed Reimbursement Methodology
- Next Steps
- Questions & Answers
• Published February 1, 2016.

• New ACA FULs, effective April 1, 2016, implementation no later than May 1, 2016.

• Mandates ingredient cost reimbursed based on actual acquisition cost.

• Defines professional dispensing fee.
FEDERAL UPPER LIMIT (FUL)

• FUL formula revised to set a floor for the FULs that are below acquisition cost as measured by a national survey of retail pharmacy acquisition costs (i.e., the NADAC).

• Compares the weighted average of AMP x 175% to the comparable generic NADAC for each FUL group.

• When the weighted average of AMP x 175% is below the generic NADAC, the FUL will be adjusted to equal the most current monthly generic NADAC rates.
EXCEPTIONS TO CALCULATING A FUL

• CMS will not calculate a FUL in the following instances:
  
  o When there are multiple NADAC prices within the FUL Product Group.
  
  o When there is not at least one corresponding NADAC NDC-11 for comparison to the FUL Product Group.
  
  o When the FUL Product Group is for a “5i drug” that is not generally dispensed to retail community pharmacies.
ACTUAL ACQUISITION COST (AAC)

- Defines AAC to mean the agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.

- Replaces estimated acquisition cost (EAC) with AAC.

- Explains that the change to an AAC model of reimbursement was necessary as it represents a more accurate reference price to be used by states to reimburse providers for drugs.
Examples of how a state can implement an AAC model of reimbursement include, but are not limited to, the following:

- Developing a state survey of retail pharmacy providers’ pricing.

- Utilizing a national survey of retail pharmacy providers’ pricing, such as the National Average Drug Acquisition Cost (NADAC).

- Utilizing published compendia prices, such as the Wholesale Acquisition Cost (WAC) (States will be expected to make adjustments to this benchmark to reflect discounts and other price concessions in the marketplace).

- Utilizing average manufacturer price (AMP) based pricing.
REIMBURSEMENT REQUIREMENTS

• Requires that when states propose changes to either the ingredient cost or professional dispensing fee, states must consider both to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Social Security Act (the Act).

• When proposing reimbursement changes, states are required to submit a state plan amendment (SPA) to CMS for review which includes a survey or other reliable data to support any proposed changes to either or both of the components of the reimbursement methodology.
• Finalizes replacing “dispensing fee” with “professional dispensing fee”.

• Reinforces CMS’ position that the fee to dispense the drug to a Medicaid beneficiary should reflect the pharmacist’s professional services and costs as defined in 42 CFR § 447.502.

• States have the flexibility to set their professional dispensing fee.
CMS has allowed state Medicaid programs to use several options for evaluating their professional dispensing fees:

- In-state cost of dispensing survey
- National survey
- Regional / neighboring state survey

Of all these potential options, an in-state cost of dispensing survey is the most reliable and defensible method for evaluating the professional dispensing fee.
• Requires that the state plan describes the agency’s payment methodology for prescription drugs, including the agency’s payment methodology for drugs dispensed by all the following:

• A covered entity described in section 1927(a)(5)(B) of the Act (340B covered entity pharmacy).
  
  □ Covered entities are required to either carve out or carve in all prescriptions.
• A contract pharmacy under contract with a 340B covered entity described in section 1927(a)(5)(B) of the Act.

• An Indian Health Service, Tribal and Urban Indian pharmacy (I/T/U).
In accordance with the requirements, the state’s payment methodology for drugs dispensed by 340B covered entities, 340B contract pharmacies, and I/T/U pharmacies must be in accordance with the definition of AAC in the final regulation.

- For drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price plus professional dispensing fee.

- For drugs purchased outside the 340B program, the reimbursement should not exceed the provider’s AAC plus professional dispensing fee.

- For drugs purchased through the Federal Supply Schedule (FSS), reimbursement should not exceed the FSS price plus professional dispensing fee.
Maryland Medicaid has determined the primary basis for AAC reimbursement will be:

NADAC

if NADAC unavailable, SAAC will be calculated
Acquisition based pricing index provided by CMS.

Random nationwide sample of Retail Community Pharmacies which includes Independent and Chain pharmacies in all states (excludes closed door pharmacies).

Monthly survey requests invoice purchase records from most recent 30 day period.
NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC)

- NADAC calculation excludes: Discounts, Rebates, Chargebacks, Free Goods:
  - Typically not included on invoice.
  - Typically not correlated to individual drug products or invoices.

- NADAC rates are calculated for Brand and Generic CMS covered outpatient drugs:
  - 89% of Brand claims and 79% of Brand expenditures
  - 98% of Generic claims and 94% of Generic expenditures
NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC)

• NADAC rates are updated on a weekly and monthly schedule:
  o Weekly updates occur for help desk calls and Brand drugs to reflect changes in published pricing.
  o Monthly updates occur to reflect the results of the ongoing monthly acquisition cost survey for Brand and Generic drugs.
MARYLAND (SAAC) STATE ACTUAL ACQUISITION COST

- Items without a NADAC will be reimbursed using lower of logic:
  - SAAC;
  - WAC + 0%; or
  - FUL
  * Does not apply to Clotting Factor

- SAAC is an acquisition pricing benchmark reflective of MD Medicaid participating pharmacies purchase records.

- SAAC rates will be calculated for MD Medicaid covered drugs/products without a NADAC.

- Pharmacies will be surveyed every 6 months requesting invoice purchase records from the most recent 30 day period.

- SAAC rates will be updated on a weekly basis to reflect changes in published pricing or rate updates due to help desk calls.
MD SAAC SURVEY PROCESS

• Initial Survey
  o MD pharmacy providers were selected to participate.
  o Provider survey letters were mailed December 30, 2016.
    – All brand and generic drug purchases from all wholesale suppliers.

• Ongoing Surveys
  o Randomly selected providers will be surveyed every 6 months.
    – Chain/Independent
    – Urban/Rural
  o Requesting all invoices from previous month’s purchases
• Providers are requested to submit invoices by January 16, 2017.
  o Invoices can be submitted in printed or electronic format and should include:
    – National Drug Code (NDC)
    – Purchase price of drug (drug ingredient cost only)
    – Quantity purchased
    – Purchase date for each product
    – “Item number” to NDC crosswalk, if item numbers or other proprietary nomenclature is used on invoices
  o Wholesale suppliers may submit purchasing history directly to Myers and Stauffer.
SUMMARY

• February 1, 2016
  o Final Rule published requiring states to replace Estimated Acquisition Cost with Actual Acquisition Cost.

• December 30, 2016
  o Surveys mailed to Maryland Medicaid participating pharmacy providers requesting invoice records from December 1, 2016 – December 31, 2016.

• January 16, 2017
  o Invoice records due to Myers and Stauffer, LC.
**PROPOSED REIMBURSEMENT METHODOLOGY**

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<tr>
<th>Prescription</th>
<th>Condition</th>
<th>Payment is Lesser Of</th>
<th>Allowable Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regardless of Drug Category</td>
<td>At least one NADAC price available</td>
<td>• U/C</td>
<td>NADAC (NDG or NDB)</td>
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<td></td>
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<td>• Allowable Cost + Prof. Disp. Fee ($10.49)</td>
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<tr>
<td>Regardless of Drug Category</td>
<td>No NADAC available, but WAC and/or SAAC available</td>
<td>• U/C</td>
<td>Lesser Of:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Allowable Cost + Prof. Disp. Fee ($10.49)</td>
<td>1. SAAC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. WAC + 0%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>3. ACA FUL</td>
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<tr>
<td>Regardless of Drug Category</td>
<td>No NADAC, WAC, or SAAC available</td>
<td>Claim will deny</td>
<td>State will manually price</td>
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*Professional Dispensing Fee to a pharmacy for recipients residing in nursing facilities will be $11.49.*
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<tbody>
<tr>
<td>DAW 1 and DAW 6 Claims</td>
<td>NADAC (NDB) price available</td>
<td>• U/C</td>
<td>NADAC (NDB)</td>
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<td>2. SAAC</td>
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<tr>
<td>340B Claims</td>
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<td>Allowable Cost + Prof. Disp. Fee ($10.49)</td>
<td>340B AAC</td>
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*Professional Dispensing Fee to a pharmacy for recipients residing in nursing facilities will be $11.49.*
NEXT STEPS

• April 1, 2017
  o DHMH must comply with revisions to reimbursement methodology.

• Spring/Summer 2017
  o Specialty Study
    ▫ Cost of Dispensing Survey
    ▫ AAC Ingredient Cost Study

• Future Activities
  o Ongoing SAAC surveys to support products without a NADAC.
  o COD survey for retail community pharmacies.
MD SAAC Survey Help Desk

800-591-1183

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