Welcome

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

Athos Alexandrou, MBA
Director
Maryland Medicaid Pharmacy Program

June 21, 2017
• Opening Remarks

• Introductions
MYERS AND STAUFFER STAFF

• T. Allan Hansen – Principal
• Darold Barnes, RPh – Senior Manager
• Jennifer Murray, PharmD, CGP – Senior Manager
• Matt Hill, CPhT - Manager
AGENDA

• Overview
• Survey Objectives
• Centers for Medicare and Medicaid Services; Medicaid Program; Covered Out Patient Drugs; Final Rule (42 CFR Part 447) Published February 1, 2016 (CMS Final Rule)
• Specialty Cost of Dispensing (COD) survey
  – Survey Approach
  – Draft Survey Tool
  – Survey Process
• Specialty State Actual Acquisition Cost (SAAC) survey
  – Overview
  – Timeline
  – Submissions
• Next Steps
• Questions & Answers
Specialty drug criteria and provider selection:

There is no singular definition of “specialty” in the pharmacy industry or for governmental agencies. For the purpose of this process, “specialty” refers to drugs that do not have a NADAC, meet the definition of a covered outpatient drug as defined in 42 CFR 447.502, and are not dispensed by a retail community pharmacy but are dispensed primarily through the mail.

Survey Participation is mandatory:

Participation and document production is required under COMAR 10.09.03.03E and COMAR 10.09.03.07A.
Objectives of Specialty Pharmacy surveys:

To determine the cost of dispensing specialty prescription drugs to Medicaid participants by providers in the Maryland Medicaid Pharmacy Program.

To establish a state actual acquisition cost (SAAC) pricing benchmark for specialty drugs reflective of Maryland Medicaid participating pharmacies’ purchase records.
CMS FINAL RULE

• 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).

• Replaces “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.
  – Gives states the flexibility to set their professional dispensing fee but requires a basis in survey data.
“Professional dispensing fee means the fee which —

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist’s time in checking the computer for information about an individual’s coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.”

1 See “Medicaid Program; Covered Outpatient Drugs.” (CMS-2345-FC) Federal Register, 81: 20 (1 February 2016) p 5349.
Survey Approach

- Collects actual (not estimated) historical overhead and labor costs
- Survey method consistent with CMS guidelines for components of professional dispensing fee
- Follows Medicare cost reporting principles for allocating allowable costs
- All reported overhead expenses will be evaluated and allocated if applicable to the cost of dispensing
- All labor expenses (including draws, bonuses, profit sharing, pension, and benefits) will be evaluated and allocated if applicable to the cost of dispensing
- Labor reporting includes a breakdown of percent of time conducting prescription dispensing activities
- All providers are requested to submit source documentation used to complete the cost of dispensing survey (i.e. financial statements, prescription dispensing logs, and store blueprints or diagrams).
Draft Survey Tool

- Page 1: Declaration of owner and/or preparer and fiscal year
  - Complete attestation of the submitted information on the cost of dispensing survey.
  - Designate the fiscal year that is being used to complete all sections of the cost of dispensing survey.
Draft Survey Tool

- **Page 2: Pharmacy Attributes**
  - Report new, refill, and total prescriptions for the same fiscal year noted on page 1.
  - Report pharmacy only sales and total sales for the same fiscal year noted on page 1.
  - Report the pharmacy department and total facility square footage.
  - Report breakdown of percent of prescriptions dispensed and percent of payments received.
  - Report other general attributes.
Draft Survey Tool

• Page 3: Pharmacy Attributes (continued)
  
  – General information about the location being surveyed
  
  – Can add additional narrative or attach additional pages to identify any other areas that contribute significantly to the provider’s cost of dispensing
• Page 4: Specialty Product Breakdown
  – Include each prescription in only one category from the top of the page down (i.e. if clotting factor, and prefilled, place only in clotting factor)
  – Total number of prescriptions and dollar amount of sales must reconcile back to reported items on page 2.
  – Number of prescriptions and dollar amount of sales must be from the same fiscal year noted on page 1.
Draft Survey Tool

Page 5: Personnel Costs

- Include number of FTE’s and salary for each group of employees.

- Include percent of time each group of employees is doing direct dispensing activities, prescription related activities, or non-prescription related activities.

- Include the pension and profit sharing and employee benefits in aggregate on lines 14 and 15, respectively, for all employees.

- Personnel costs should be reported for the same fiscal year noted on page 1.
Draft Survey Tool

- **Page 6: Overhead Expenses**
  - Includes most commonly reported expense items along with the reference to tax form lines.
  - Only use a tax return if the tax return represents the expenses for a single location. Otherwise use internal financial documentation.
  - Expenses should be reported for the same fiscal year noted on page 1.
  - Myers and Stauffer can complete pages 6, 7, and 8 when the provider submits internal financial statements or a tax return that is for only the location being surveyed.
Draft Survey Tool

• Page 7: Overhead Expenses (continued)
  - Non-labor expenses not included elsewhere to be included on this page.
  - Provide a description of the expense and the dollar amount.
  - For corporate allocations include a description of items included in the allocation and method for allocation.
  - Expenses should be reported for the same fiscal year noted on page 1.
Draft Survey Tool

- Page 8: Reconciliation page
  - Reconcile cost of dispensing survey to source documentation
  - Source documentation should be for the fiscal year noted on page 1 of the survey.

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SPECIALTY COD SURVEY

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MARYLAND MEDICAID PHARMACY PROGRAM - FFS
MANDATORY SPECIALTY COST OF DISPENSING SURVEY

SECTION III – RECONCILIATION WITH FINANCIAL STATEMENT OR TAX RETURN

The purpose of this reconciliation is to ensure that all expenses have been included and that none have been duplicated. Consider these lines using the same fiscal year which was used to report overhead and labor expenses.

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost Survey Amounts</th>
<th>Financial Statement or Tax Return Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1(a)</td>
<td>Total Expenses per Financial Statement or Tax Return</td>
<td></td>
</tr>
<tr>
<td>1(b)</td>
<td>Total Labor Expenses (total from page 5, line 18)</td>
<td></td>
</tr>
<tr>
<td>1(c)</td>
<td>Overhead Expenses (total from page 6, line 11)</td>
<td></td>
</tr>
<tr>
<td>1(d)</td>
<td>Overhead Expenses, Continued (total from page 7, line 13)</td>
<td></td>
</tr>
<tr>
<td>1(e)</td>
<td>Total Expenses per Cost Survey (add Lines 1(b), 1(c), and 1(d))</td>
<td></td>
</tr>
<tr>
<td>1(f)</td>
<td>Specify Items with Amounts that are on Cost Survey but not on Financial Statement or Tax Return</td>
<td></td>
</tr>
<tr>
<td>1(g)</td>
<td>Specify Items with Amounts that are on Financial Statement or Tax Return but not on this Cost Survey</td>
<td></td>
</tr>
<tr>
<td>1(h)</td>
<td>Specify Items with Amounts that are on Financial Statement or Tax Return but not on this Cost Survey</td>
<td></td>
</tr>
<tr>
<td>1(i)</td>
<td>Total (add Lines 1(a) to 1(h)); Column Totals Must Be Equal</td>
<td></td>
</tr>
</tbody>
</table>

If you avoid a tax form to complete the cost of dispensing survey, the total expenses per tax return will be found on the following lines for 2018 tax forms:

- 1040C - line 28
- 990T - line 21
- 1120 - line 27
- 1120S - line 20

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Survey Process

- Finalize survey tool in collaboration with MMPP and stakeholders
- Distribute survey to selected pharmacy providers
  - Four weeks allotted for survey response
  - Providers will be requested to submit supporting documentation (i.e. financial statements, prescription dispensing logs, store blueprints or diagrams).
  - Myers and Stauffer can complete the overhead expenses section and reconciliation.
  - Survey help desk will be available via toll free number or email
- Reminder letters sent to all non-respondent pharmacies
- Desk review of all submitted surveys
- Data entry and analysis
- Report of findings to MMPP
Overview

• In correlation with the specialty COD survey, Myers and Stauffer will be conducting a separate specialty SAAC survey to determine the actual acquisition cost for specialty drugs/products.

• MMPP providers dispensing a high volume of specialty drugs/products will be selected to participate.

• The MD specialty SAAC survey is independent of the June SAAC survey you may have received. If your pharmacy is selected for both surveys, a submission for each survey is required.
SPECIALTY SAAC SURVEY

TIMELINE

• Provider survey letters will be mailed August 1, 2017.

• **Two** months of invoices: May 1, 2017 – June 30, 2017 will be requested.

• All brand and generic drug/product purchases from **all** wholesale suppliers and drug manufacturers will be requested.

• Providers will be required to submit by August 15, 2017.
SUBMISSIONS

• Invoices can be submitted in printed or electronic format and should include:
  – National Drug Code (NDC)
  – Purchase price of drug/product (drug/product 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
SUBMISSIONS

• Wholesale suppliers may submit purchasing history directly to Myers and Stauffer on behalf of the pharmacy.

• Submissions are to be sent directly to Myers and Stauffer.

Myers and Stauffer LC
Attention: MD Pharmacy Survey
9265 Counselors Row, Suite 100
Indianapolis, IN 46240-6419

-OR-

pharmacy@mslc.com

Please indicate “Maryland Pharmacy Survey” in the subject line
QUESTIONS/COMMENTS ON DRAFT COD SURVEY

Questions or comments on the draft cost of dispensing survey tool should be submitted to Myers and Stauffer by June 30, 2017 to the phone number or email address below. Help desks will be operated to support both surveys during normal business hours and can be reached at the phone numbers and emails addresses listed below.

Cost of Dispensing Survey
800-374-6858
-OR-
disp_survey@mslc.com

MD SAAC Survey Help Desk
800-591-1183
-OR-
mdpharmacy@mslc.com
NEXT STEPS

• **June 30, 2017**
  • Stakeholders submit questions or comments to Myers and Stauffer

• **Summer 2017**
  • Finalize Specialty Cost of Dispensing Survey Tool
  • Conduct Specialty Cost of Dispensing Survey
  • Conduct Specialty SAAC Survey

• **Future Activities**
  • Ongoing SAAC surveys and specialty SAAC surveys to support drugs/products without a NADAC.
  • COD survey for retail community pharmacies.