

Welcome





Larry Hogan, Governor Boyd Rutherford, Lt. Governor Dennis Schrader, Secretary



MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE





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





OVERVIEW

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.





SURVEY OBJECTIVES

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.

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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.





CMS FINAL RULE

"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 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

¹See "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.

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The following information is from fiscal / tax year ending*

Complete these forms using your most recently completed fiscal year for which financial records are available and complete (e.g., December 31, 2016, or December 31, 2015, if 2016 records are not yet complete). (Include month/day/year).* If your pharmacy has had a change in ownership or has not completed a fiscal year with at least 6 months of financial information, please call Myers and Stauffer at (800) 374-6858 to discuss you status.





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.



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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

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

(i)	Do you own your building or lease from a related party (i.e., and refer to page 6, line 5 for instructions for reporting rent			i, or related c	orporationy	ii so, iiidik j
1000	1. 🗆 Yes 2. :	⊐ No	9 0.85			
(i)	How many hours per week is your pharmacy open?	Hours			/	
(k)	How many years has a pharmacy operated at this location?		Years			
(1)	Do you provide 24-hour emergency services for pharmaceut	icals?		1. 🗆 Yes	2. 🗆 No	
_				201111		CONTRACTOR OF THE OWNER OWNER OF THE OWNE

If your pharmacy dispenses prescriptions to long-term care facilities, complete lines (m) through (o).

(m)	What is the approximate percent of y homes?%	our prescript	ions dispensed to long-term care faciliti	es or assisted living
	Do you dispense in unit dose packagir	ig to long-ter	rm care facilities (e.g., medisets, blister p	acks, etc.)?
(n)	1. 🗆 Yes		2. 🗆 No	
	What is the approximate percent of a	Il prescriptio	ns dispensed in unit dose packaging?	%
(o)	If you provide unit dose packaging, wi	nat percent o	of unit dose packaging is:	
(0)	1. Purchased from manufacturers	%	2. Prepared in the pharmacy	%

If your pharmacy provides delivery, mail order, specialty or compounding services, complete lines (p) through (s) as applicable.

(p)	What percent of total prescriptions filled are delivered?%		
(q)	What percent of Medicaid prescriptions filled are delivered?%	-	
	Does your pharmacy deliver prescriptions by mail (U.S. Postal Service, FedEx, UPS, etc.)?	1. 🗆 Yes	2. 🗆 No
(г)	If yes, what is the approximate percentage of the total number of prescriptions that are delivered by mail? $\%$		
	Does your pharmacy prepare and dispense compounded prescriptions?	1.⊡ Yes	2. □ No
(s)	If yes, what is the total number of prescriptions dispensed that are compounded?		
	For prescriptions that are compounded, what is the average number of minutes spent preparing a and technicians? Pharmacist: Technician:	prescription	by pharma

SECTION IB -- OTHER INFORMATION

SECTION IA -- PHARMACY ATTRIBUTES, CONTINUED

List any additional information you feel contributes significantly to your cost of filling a prescription. Attach additional pages if needed.







Draft Survey Tool

- 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.

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

Page 4

SECTION IC -- PHARMACEUTICAL PRODUCT BREAKDOWN

Provide breakdown of the speciality and non-speciality products dispersed in your pharmacy or ign the categories destribe below or other categories asymptoprian. Prove report the number of precurptions and oblig amount of visits in one category only. The cample non-activity of the categories prefiled, however place it in "cloting factor or derivatives" only and nati in "prefiled or ready to night products". Humber of precurptions and doing and alsels should analy taking factor active priority for support and marking and the precurptions and seter synather and the priority and the precurption and active prefiled in a social factor with the dispension of the categories and the precurption and active precision of the precision and the precision of the categories and the precision of the precision of the categories and the precision of the categories and the precision of the precision of the categories and the categories and the precision of the categories and the precision of the categories and the precision of the categories and the categories a

Product Category		Dollar Amount of Sales	Line No.
Infusion Products			
Compounded infusion products			(1a)
Total Parenteral Nutrition (TPN) products			(15)
Clotting factors or cerivatives			(1c)
Infusion supplies (e.g., tubing, needles, catheter flushes, IV site dressings, etc.)			(1d)
Total for Infusion Products			(iv)
Specialty			
Prefiled or ready to inject products			(2a)
Orals			(20)
Total for Specialty			(2c)
Non-specialty			
Orals	1		(3a)
Topica s			(35)
Injectao es			(3c)
Compounded (non-infusion)			(3d)
Entera nutrition			(3e)
Other (including ophtha mic, otic, etc.)			(3f)
Total for Non-specialty			
Total (Should reconcile to prescriptions and Pharmacs			1
Department, sales reported in Section 14		r	(4)
Additional Pharmacy Attribute Questions for Pha	armacies Dispensing Specia	ty Products	
(a) - Are supplies provided for patient use and ad-			tc. included in the
cost of goods sold reported in section IA?		No	
(b) - Pease provide the total doi an amount of exp (c) Are supplies provided for patient administration as DME, etc.? 1. D Yes 2.0			
(d) What percentage of prescriptions dispensed w reporting requirements?	ere for products with REM	s (Risk Evaluation and Miti	gation Strategy)
(e) What percentage of prescriptions dispensed w place?	ere for products that had p	atient monitoring and com	pliance activities in
(f) What percentage of prescriptions dispensed we etc.)?	ere for products that had s	ecial storage requirement	s (e.g., refrigeration,

(g) For how many states does this facility ship specialty products to Medicaid participants.

SECTION ID - OTHER INFORMATION

Use the section below to provide additional narrative description of the speciality products and services that are provided by your pharmacy. Use this section to describe any patient monitoring programs, patient compliance programs, case management services or disease management services provid by your pharmacy. Describe any specialitie despinent use do in your pharmacy. Attach additional pages as successary.





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.

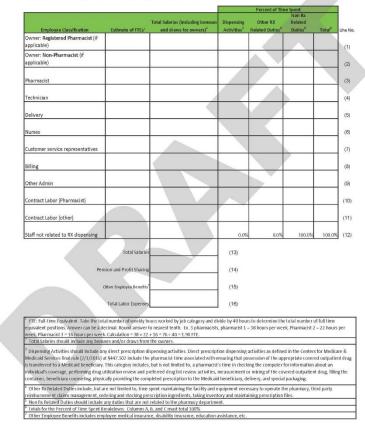


MARYLAND MEDICAID PHARMACY PROGRAM - FFS MANDATORY SPECIALTY^A COST OF DISPENSING SURVEY

SECTION IIA -- PERSONNEL COSTS

age 5

Complete each employee classification line in aggregate. If there are no employees in a specific category, please leave blank. Provide your best estimate of the percentage of time spent working in each category, the rows must equal 100%. Complete these forms using the same fixed uper as listed on page 1 and used for reporting overhead expenses.





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.



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

SECTION IIB -- OVERHEAD EXPENSES

Page

Complete this section using your internal financial statement or tax return for the <u>fiscal year ending listed on Page 1</u>. You should only use a tax return if the only store reported on the return is the store being surveyed. If you are using a tax return, the line numbers in the left columns correspond to federal income tax return lines. Use your most recently completed fiscal year for which financial records are available and completed (e.g., December 31, 2016, or December 31, 2015, if 2015, if 2015 records are not yet complete). If you prefer, you may submit a copy of your financial statement and/or tax return (including all applicable schedules) and Myers and Stauffer can complete Sections IIB and III (pages 6, 7, and 8).

Notes about tax return line references

Form 1040, Sched C, line 27a is for "other expenses" and a detailed breakdown of this category is typically reported on page 2, Part V of the form. Form 1065 (line 20), Form 1120 (line 26) and Form 11205 (line 19) are for "other deductions" and there are typically detailed breakdowns of the expenses in this category in the "Statements" attached to the returns.

201	5 Tax	Form	-				Г
1040 Schedule	1065	1120	11205	Round all amounts to nearest dollar or whole number.	Expense Amount Reported	Myers and Stauffer Use Only	
13	16a	20	14	Depreciation (this fiscal year only - not accumulated)			
23	14	17	12	(a) Personal Property Taxes Paid			
23	14	17	12	(b) Real Estate Taxes		80 (Z	
23	14	17	12	(b) Real Estate Taxes (c) Payroll Taxes		6 1075 - 2011 -	
				Any other taxes should be itemized separately on page 7			
				Rent - Building (if building is leased from a related party then report ownership			
20b	13	16		expenses of interest, taxes, insurance and maintenance)			
20a	13	16	-	Rent - Equipment and Other			
21	11	14	1	Repairs & maintenance	2	·	
15	20*	26*	1.2.00	Insurance (other than employee medical)		·	
16a&b	15	18	13	Interest	-		
17	20*	26*	19*	Legal and Professional Fees	-	č., <u></u> ,	
27a*	20*	26*	19*	Dues, Publications, and Subscriptions	-	· · · · · · · · · · · · · · · · · · ·	
27a*	12	15	10	Bad Debts (this fiscal year only - not accumulated)			
n/a	n/a	19	n/a	Charitable Contributions			
25	20*	26*	19*	Utilities (a) Telephone			
25	20*	26*	19*	(b) Heat, Water, Lights, Sewer, Trash and other Utilities			
18&22	20*	26*	19*	Operating and Office Supplies (exclude prescription containers and labels)			
8	20*	22	16	Advertising/Marketing			
27a*	20*	26*	19*	Computer Expenses (systems, software, maintenance, etc.)			
9,27a*	20*	26*	19*	Prescription Delivery Expenses (wages to a driver should only be reported on pg. 5)			
27a*	20*	26*	19*	Prescription Containers and Labels			
ACCOUNTS.	20*	26*	19*	Travel, Meals and Entertainment			
27a*	20*	1.52	100	Switching / E-Prescribing Fees		1	
27a*	20°	115.		Security / Alarm		Si (
27a*		122110	D.	Bank Charges		10	
27a*	20*		-	Credit Card Processing Fees		· · · · · · · · · · · · · · · · · · ·	
27a*	20*			Interior Maintenance (housekeeping, janitorial, etc.)			
27a*	20*		1100	Exterior Maintenance (lawn care, snow removal etc.)	-		
27a*	20*		-	Pharmacy Licenses / Permits			
27a*	20*			Employee Training and Certification		(),	
-10	20			Continuing Education	-		



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.

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

SECTION IIB -- OVERHEAD EXPENSES, CONTINUED (Round all amounts to nearest dollar or whole number.)

Other non-labor expenses not included on lines (1) through (30)

Examples: Franchise fees, other taxes not reported in Section IIB (a) (page 6), accreditation and/or certification fees, restocking fees, postage, administrative expenses, amoritization, etc. Specify each item and the corresponding amount. Note that labor expenses are reported in Section IIA (page 5). For corporate overhead expenses allocated to the individual store, please attach documentation to establish the expenses included in the allocation and describe the allocation basis.

			CONTRACTS.
Expense Description	Amount	Stauffer Use	Line No
		>	(32a)
			(32b)
			(32c)
			(32d)
		P	(32e)
			(32f)
			(32g)
			(32h)
	<u> </u>		(32i)
	· · · · · · · · · · · · · · · · · · ·		(32j)
			(32k)
			(321
		(atomicanicanica)	(32 m
		33	(32n
			(320
			(32p
			(32q
		1	(32 r
			(32s
			(32t)





MARYLAND Department of Health & Mental Hygiene

Page 7

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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.

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

Page 8

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. Complete these forms using the same fiscal year which was used to report overhead and labor expenses.

	Cost Survey Amounts	Financial Statement of Tax Return Amounts
Total Expenses per Financial Statement or Tax Return ²	cost survey remounts	
Total Labor Expenses (total from page 5, line 16)		
Overhead Expenses (total from page 6, line 31)		
Overhead Expenses, Continued (total from page 7, line 33)		
Total Expenses per Cost Survey [add Lines (2), (3), and (4)]		
Specify Items with Amounts that are on Cost Survey but not on		
Financial Statement or Tax Return		
		No. 1
And the second s		
		1
		<u> </u>
pecify Items with Amounts that are on Financial Statement or Ta	.	
eturn but not on this Cost Survey		
	-	
A REAL PROPERTY AND A REAL		
Total [add Lines (1) to (7e)] Column Totals Must be Equal		
If you used a tax form to complete the cost of dispensing survey,	the total expenses per tax	return will be found on
he following lines for 2016 tax forms:		
Second a March 1		
1040C - Line 28		
1065 - line 21		
1120 - line 27		
11205 - line 20		

^A There is no singular definition of "speciality" in the pharmacy industry or for governmental agencies. For the purpose of this cost of dispensing survey and process, "speciality" in the pharmacy industry or to the verse NADAC, meet the definition of a covered outpatient drug as defined in 42 CF R447.502, and are not dispensed by a retail community pharmacy but are dispensed primarily through the mail.





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.

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TIMELINE

- Provider survey letters will be mailed August 1, 2017.
- <u>Two</u> months of invoices: May 1, 2017 June 30, 2017 will be requested.
- All brand and generic drug/product purchases from <u>all</u> 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

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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 SurveyMD SAAC Survey Help Desk800-374-6858800-591-1183-OR--OR-disp_survey@mslc.commdpharmacy@mslc.com

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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.





Maryland Department of Health & Mental Hygiene







