Division of
Health Care
Finance & Administration

# STATE OF TENNESSEE

## Pharmacy Stakeholder Meeting

March 2nd, 2016

# AGENDA

9:30 **Welcome and Introductions**

9:35 **Review of Covered Outpatient Drug Final Rule** (CMS-2345-FC)

9:40 **Tennessee Acquisition Cost Survey Results**

- Key Definitions
- Reimbursement Methodology
- Rate Review / Help Desk Process

10:15 **Tennessee Professional Dispensing Fee Survey**

- PDF Survey Results
- Recommended Professional Dispensing Fees

10:45 **Questions and Answers**

# TENNCARE TIMELINE

## TennCare Analyses

- Dec 15 – Professional Dispensing Fee Opened
- Dec 23 – Ingredient Cost Survey Initial Letter
- Jan 20 – Extended Deadline for PDF Survey Submissions
- Jan 27 – Extended Acceptance of AAC Submissions
- Jan 20 – Feb 10 – Onsite validation of PDF Survey Results
- Feb 22 – Data Analysis and Report

## Final Rule Compliance

- Mar 1 – Initial Pricing Methodology due to Magellan RX
- Apr 1 – Go-Live and Implementation of new methodology
- Mar/Apr – TennCare continued discussions with CMS
- May 1 – Targeted Date for TennCare State Plan Amendment Submission to CMS for approval
- Jun 30 – Final Deadline for CMS SPA Submission

# QUESTIONS?

- Use the chat box function to submit your question.
- Identify your full name and pharmacy/organization you represent when submitting a question.
- We will answer as many questions as possible after presenting results from both the AAC and PDF Surveys

# COVERED OUTPATIENT DRUGS FINAL RULE (CMS-2345-FC)

- Published February 1, 2016
- New ACA FULs, effective April 1, 2016, implementation May 1, 2016
- Ingredient costs reimbursed based on actual acquisition cost
- Defines professional dispensing fee

# FEDERAL UPPER LIMIT (FUL)

- FUL formula revised and is calculated as the weighted average of AMP x 175%. If this amount is less than to the comparable generic NADAC for each FUL group, the FUL will be adjusted to equal the most current monthly generic NADAC rates.
- CMS will not calculate an FUL for the following products:
  - When there are multiple NADAC prices within the FUL Product Group.
  - When there is not at least one corresponding NADAC NDC-11 for comparison to the FUL Product Group.
  - When the FUL Product Group is for a “5i drug” that is not generally dispensed by retail community pharmacies.

# ACTUAL ACQUISITION COST (AAC)

- Replaces estimated acquisition cost (EAC) with AAC, and defined AAC to mean the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

- Examples of how a state may implement AAC reimbursement include:

  - Developing a State Survey of Retail Community providers' pricing;

  - Utilizing the CMS National Survey of retail community providers' pricing, National Average Drug Acquisition Cost (NADAC);

  - Utilizing published pricing compendia such as Wholesale Acquisition Cost (WAC), adjusted to reflect discounts and other pricing concessions in the marketplace.

# REIMBURSEMENT REQUIREMENTS

- When states propose changes to either the ingredient cost or professional dispensing fee, states must consider both to ensure total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Social Security Act.
- When proposing reimbursement changes, states 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.
- The SPA must describe the state's reimbursement methodology for covered outpatient drugs dispensed by pharmacies. The state must specifically address reimbursement for covered entities and contract pharmacies (including 340B), and Indian Health Service, Tribal and Urban Indian pharmacy (I/T/U).
- If changes made to Specialty and Clotting Factor reimbursement, State must provide data to support any proposed changes. While the State may retain their current methodology, the State must show that reimbursement is in accordance with the requirements of section 1902(a)(30)(A) of the Social Security Act (the Act)

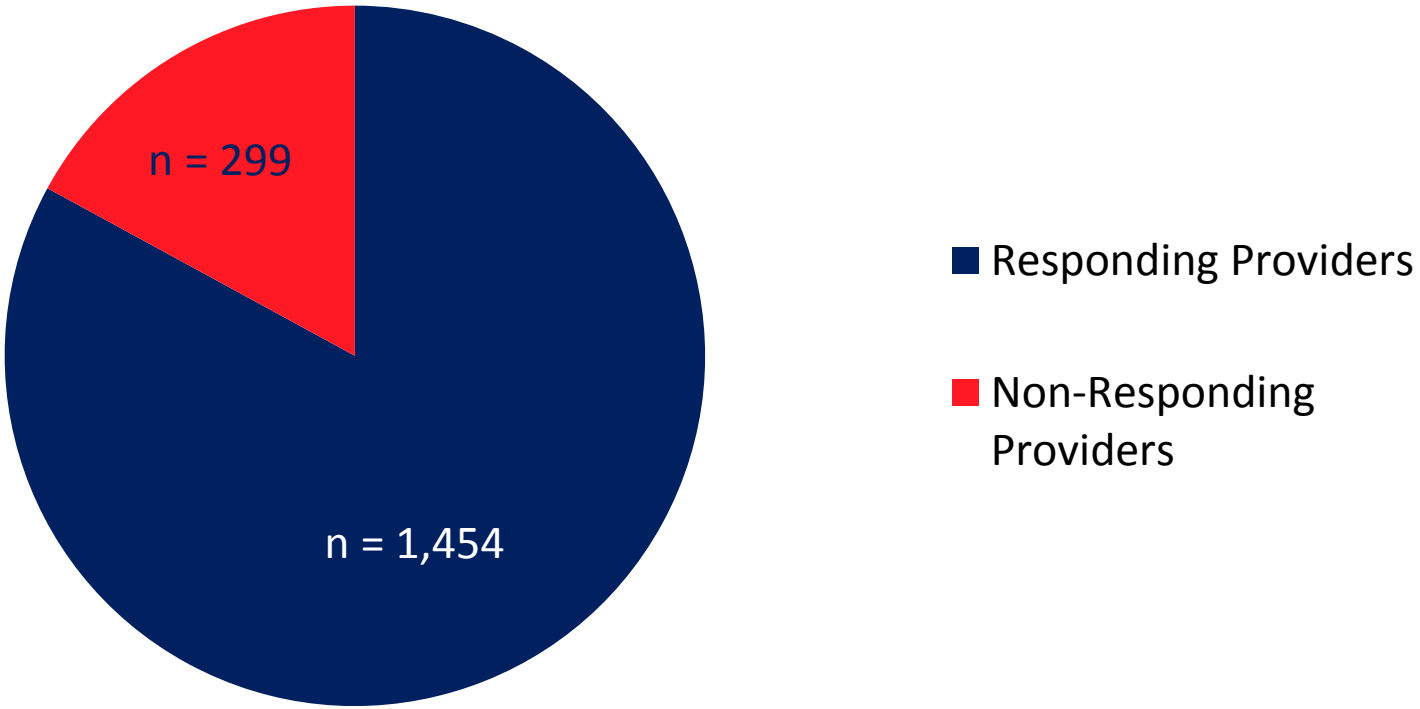
# TN AAAC SURVEY PROCESS

- Initial Survey
  - All pharmacy providers selected to participate.
  - Provider survey letters mailed December 21, 2016.
    - Invoices from December 1, 2016 – December 31, 2016 were requested.
    - All brand and generic drug purchases from all wholesale suppliers.
  - Follow up reminders were mailed January 6, 2017.
  - Surveys responses due January 18, 2017
  - Responses accepted through January 27, 2017 for use in analysis

- Ongoing Surveys
  - Randomly selected providers will be surveyed every 6 months.
    - Chain/Independent
    - Urban/Rural
  - Invoices from previous month's purchases will be requested.

# TENNCARE ACQUISITION COST STUDY

**Total AAC Survey Participation Rate = 83%**



# INGREDIENT REIMBURSEMENT METHODOLOGY

TennCare has determined the basis for AAC ingredient reimbursement will include:

- Federal Upper Limit (FUL)
- TN Average Actual Acquisition Cost (TN AAAC)
- National Average Drug Acquisition Cost (NADAC)
- WAC (adjusted to approximate acquisition cost)
- Usual and Customary (U&C)

# TN AAAC

- Acquisition based pricing submitted by specific TN Medicaid participating pharmacies.
- Pharmacies surveyed every 6 months requesting invoice purchase records from the previous month.
- State specific rates are calculated for all TN Medicaid covered drugs.
- Rates are updated on a weekly basis to reflect changes in published pricing and/or help desk calls.

# NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC)

- 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.
- NADAC rates are updated on a weekly and monthly schedule:
  - Weekly updates occur for help desk calls and Brand drugs to reflect changes in published pricing
  - Monthly updates occur to reflect the results of the ongoing monthly acquisition cost survey for Brand and Generic drugs

# SPECIALTY DRUG DEFINITON

- Definition change necessary because the great majority of products that have been listed on TennCare's Specialty Drug list are now listed on the CMS' NADAC List
  - CMS considers these products retail products, since these products are commonly dispensed via retail distribution
  - New definition will result in fewer products for TennCare to define as "Specialty Drugs"
  - Our current definition criteria will still be used, with additional parameters as follows:

# SPECIALTY DRUG DEFINITON

- A medication or a pharmaceutical product which has been prescribed for an eligible TennCare enrollee by an authorized prescriber and meets the following requirements:
  - Is not dispensed via retail pharmacies at least 51% of the time; AND
  - Does not appear on CMS' NADAC list AND
  - Meets at least two (2) of the following:
    - The cost of the medication equals or exceeds $500 for a thirty (30) day supply;
    - The medication is only approved to treat limited patient populations, indications, or conditions;
    - The medication is typically injected, infused, or requires close monitoring by a physician or clinically trained individual;
    - The medication has limited availability, special dispensing, and delivery requirements, and/or requires additional patient support – any or all of which make such drugs difficult to obtain through traditional pharmacies;

# REIMBURSEMENT DEFINITIONS

## Ambulatory Pharmacy

- Is licensed by the Tennessee Board of Pharmacy.
- Retail or any other entity that dispenses prescriptions directly to outpatient TennCare enrollees
- At least 75% of prescription volume must involve face to face interactions with enrollees.

## 340B Pharmacy

- Covered entity as per HRSA

# REIMBURSEMENT DEFINITIONS

## Long Term Care (LTC) Pharmacy

- Is licensed by the Tennessee Board of Pharmacy.
- Dispenses only to LTC or other group facilities and has a closed door facility; which means that the pharmacy does not offer retail prescription drugs of any type to retail pharmacy customers, and pharmacy is not open to public walk-in traffic.
- Requires a delivery system with the capability to provide medications to LTC or other group home facilities packaged in a manner that enables the provider to safely and legally accept unused, returned medications from the LTC/group home for credit to PBM/TennCare on a weekly or monthly basis depending on the cycle used.

# REIMBURSEMENT DEFINITIONS

## Specialty Pharmacy

- Is licensed by the Tennessee Board of Pharmacy.
- Dispenses only specialty drugs, has a closed door facility; which means that the pharmacy does not offer retail prescription drugs of any type to retail pharmacy customers, and pharmacy is not open to public walk-in traffic.
- Staffed and equipped to dispense complex medications and provide therapy management or coordination programs tailored for patients with chronic conditions.

# INGREDIENT REIMBURSEMENT METHODOLOGY

| Provider Type | First | Second | Third | Fourth | Fifth |
|---|---|---|---|---|---|
| Ambulatory – High Volume (Legend & OTC) | FUL | AAAC, if less than FUL, or if FUL does not exist. | NADAC, if lower than AAAC, or if AAAC does not exist. | WAC - 3% (Brands) WAC - 6% (Generics) | U&C, if lower |
| Ambulatory – Low Volume (Legend & OTC) | | | | | U&C, if lower |
| LTC – Closed Door | | | | | |

# INGREDIENT REIMBURSEMENT METHODOLOGY

| Provider Type | First | Second | Third | Fourth | Fifth | Sixth | Seventh |
|---|---|---|---|---|---|---|---|
| 340B | 340B Ceiling Price | HRSA 340B acquisition cost | FUL | AAAC, if less than FUL, or if FUL does not exist. | NADAC, if lower than AAAC, or if AAAC does not exist. | WAC - 3% (Brands) WAC - 6% (Generics) | U&C, if lower, plus PDF |
| Specialty | AAAC | WAC - 3% (Brands) WAC - 6% (Generics) | | | | | |
| Clotting Factor* | AAAC | Deny and request invoice, if no AAAC | | | | | |

*Please note: Reimbursement for Clotting Factor is attached to the drug, NOT the pharmacy.

# HELP DESK
# TN AAAC RATE REVIEW

- Provider submits rate review inquiry and invoice documentation.
- Help Desk performs review.
  - Assess provider's cost compared to range utilized to set rate.
  - Assess changes in market conditions.
  - Review current costs.
  - Propose action to rate review.
  - RPh reviews and confirms.
  - If rate updated, included on next TN AAAC rate file.
  - Rates NOT backdated beyond 30 days.
  - Help Desk contacts provider to reprocess claim.

# HELP DESK
# NADAC RATE REVIEW

- Provider submits rate review inquiry and invoice documentation.
- Help Desk performs review.
  - Assess provider's cost compared to range utilized to set rate.
  - Assess changes in market conditions.
  - Review current costs.
  - Propose action to rate review.
  - RPh reviews and confirms.
  - If rate updated, included on next NADAC rate file.
  - NADAC rates are NOT backdated.
  - Provider monitors NADAC file for rate adjustment.

# HELP DESK
# REQUEST FOR RATE REVIEW

**Phone: 800-591-1183**

**Email: tnpharmacy@mslc.com**

**Web: http://www.mslc.com/Tennessee**

# SUMMARY

- TennCare required to be in compliance with the CMS rule, (CMS-2345-FC), by April 1, 2017 .
- New pharmacy reimbursement methodology implementation effective April 1, 2017. Ingredient reimbursement will include consideration of the FUL, TN AAAC, NADAC, WAC, and U&C.
- TennCare currently in continued conversation for CMS to gain approval for State Plan Amendment
- Additional guidance to be provided by TennCare and Magellan on items still pending finalization with CMS
- TennCare targeting May 1 for State Plan Amendment submission

# MYERS AND STAUFFER CONTACT INFORMATION

Contact Names

Darold Barnes, RPh (Pharmacy Manager)

Adrienne McCormick, CPA (Project Manager)

Susan Parr,  CPhT (Help Desk Supervisor)

Phone: 800-591-1183

Email: tnpharmacy@mslc.com

MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

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# THANK YOU

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# STATE OF TENNESSEE

## Cost of Dispensing Survey

# Cost of Dispensing Survey
## Professional Dispensing Fees

Reflect professional services and costs associated with filling a Medicaid prescription

Not intended to offset loss of payment for ingredient cost

Appropriate to ensure adequate access

Various data-driven methodologies will be considered by CMS

State flexibility to adjust reimbursement for certain provider types and services

# Cost of Dispensing Survey

## CMS Cost Principles

### REASONABLE AND NECESSARY EXPENSES

**Professional dispensing fee 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.
- The Preamble of the final rule clarifies that CMS does not identify profit in the definition of professional dispensing fee.

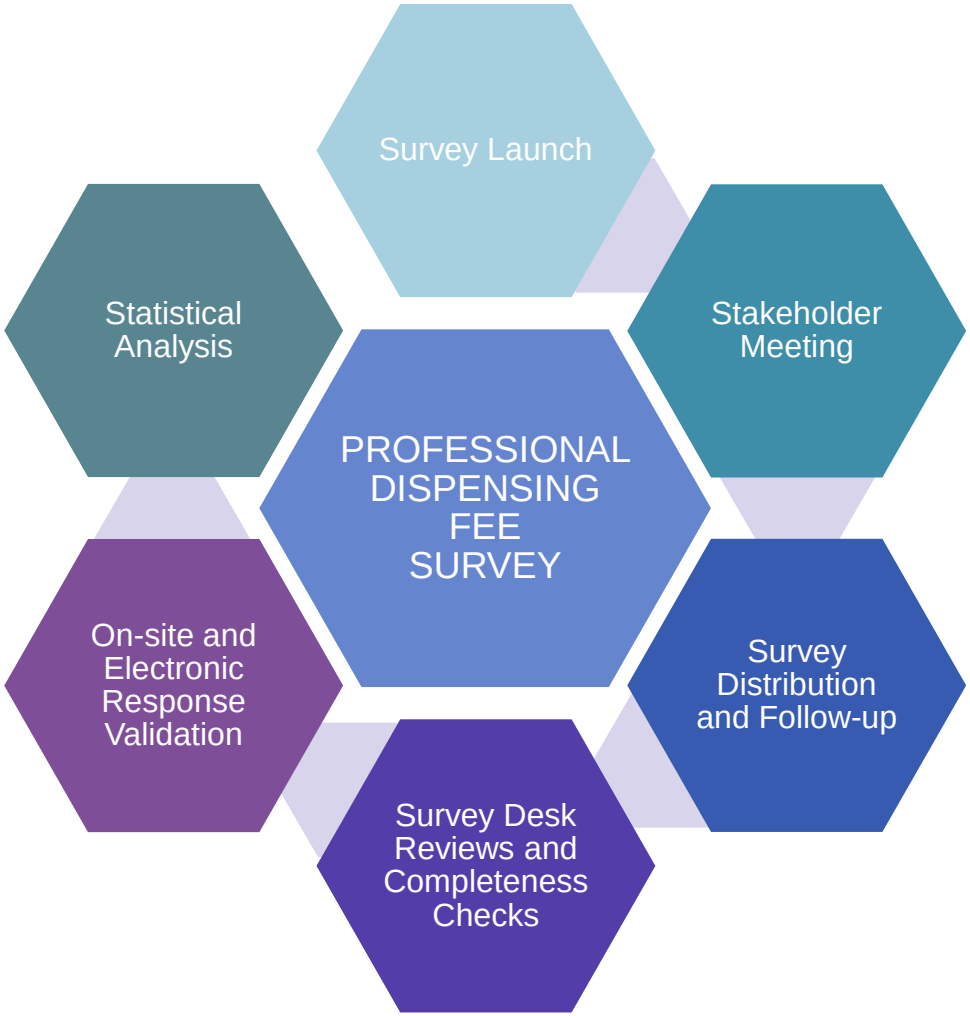
**States retain the flexibility to create a differential professional dispensing fee reimbursement per provider delivery type.**

**The analysis is meant to inform policy:**

Mercer has used and relied upon data supplied by TennCare and by the pharmacies participating the TennCare program. TennCare and participating pharmacies are responsible for the validity and completeness of this supplied data and information.

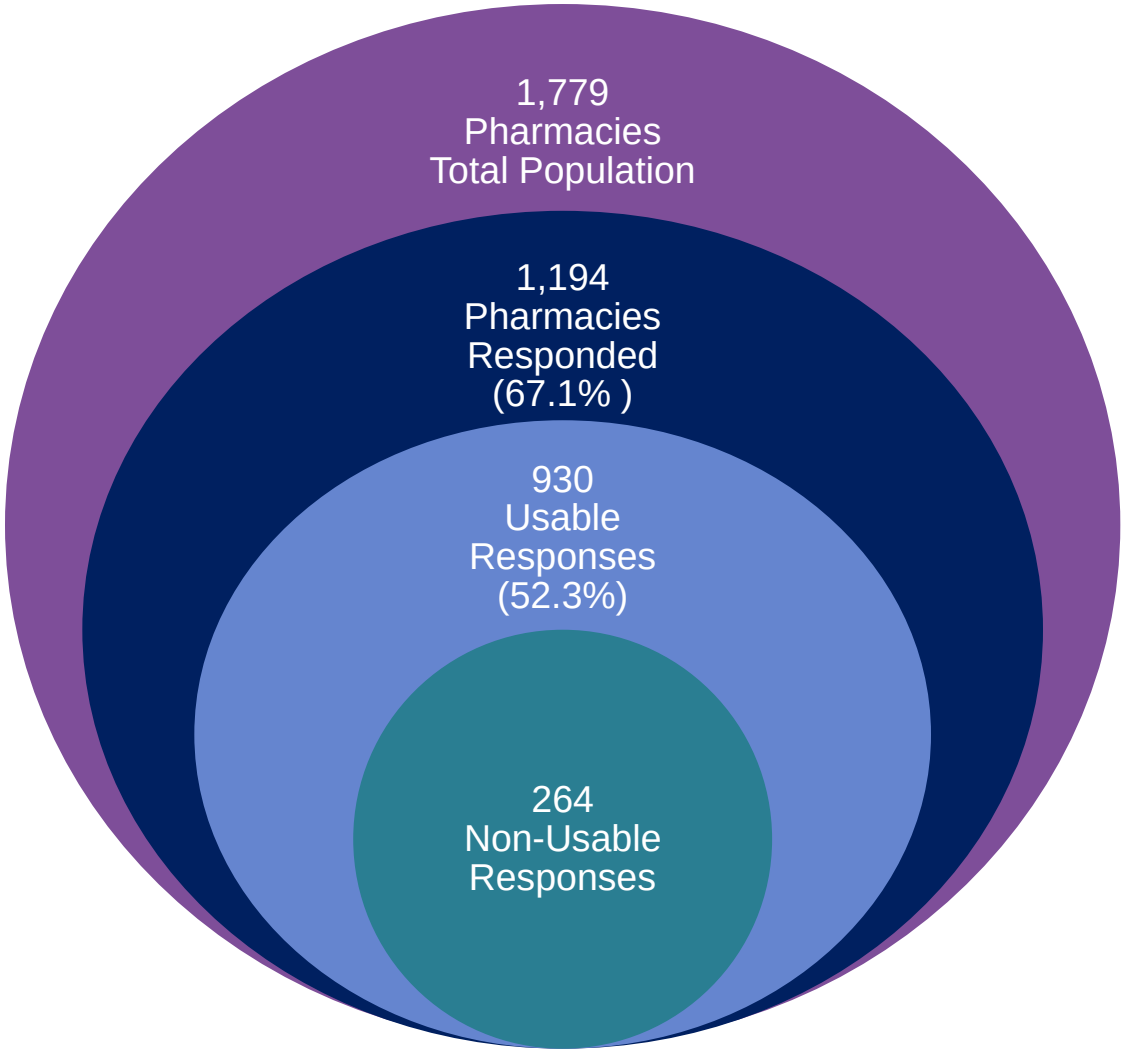
# Cost of Dispensing Survey

## Process



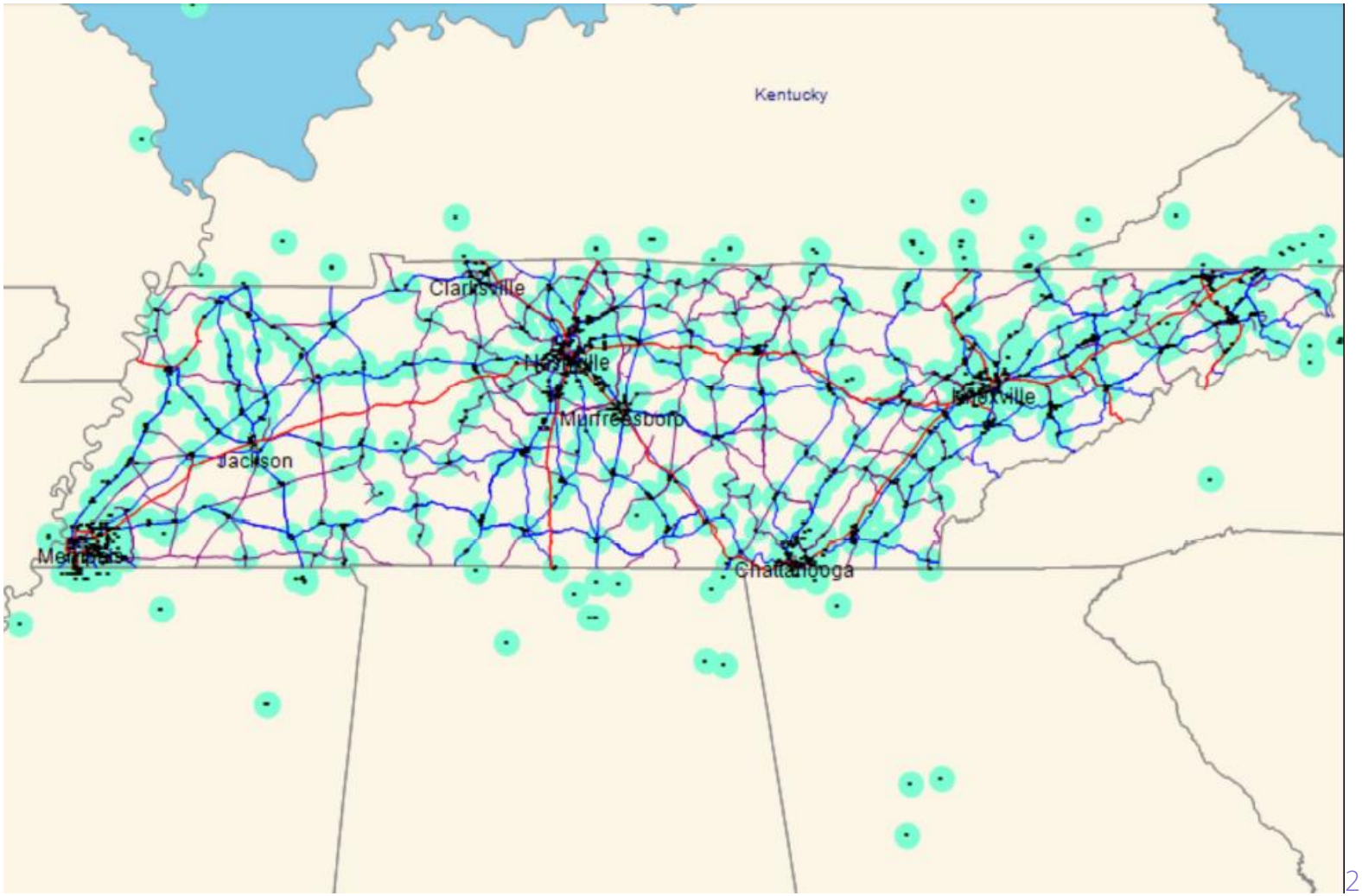
# Cost of Dispensing Survey

## Response Detail

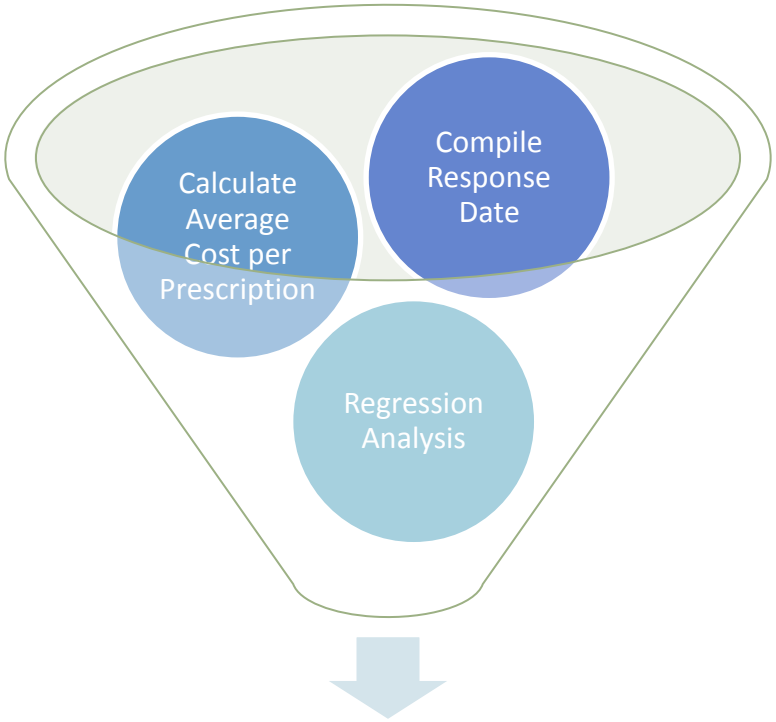



TennCare PDF Survey Response Rate = 67.1%

# Cost of Dispensing Survey
## Response Map



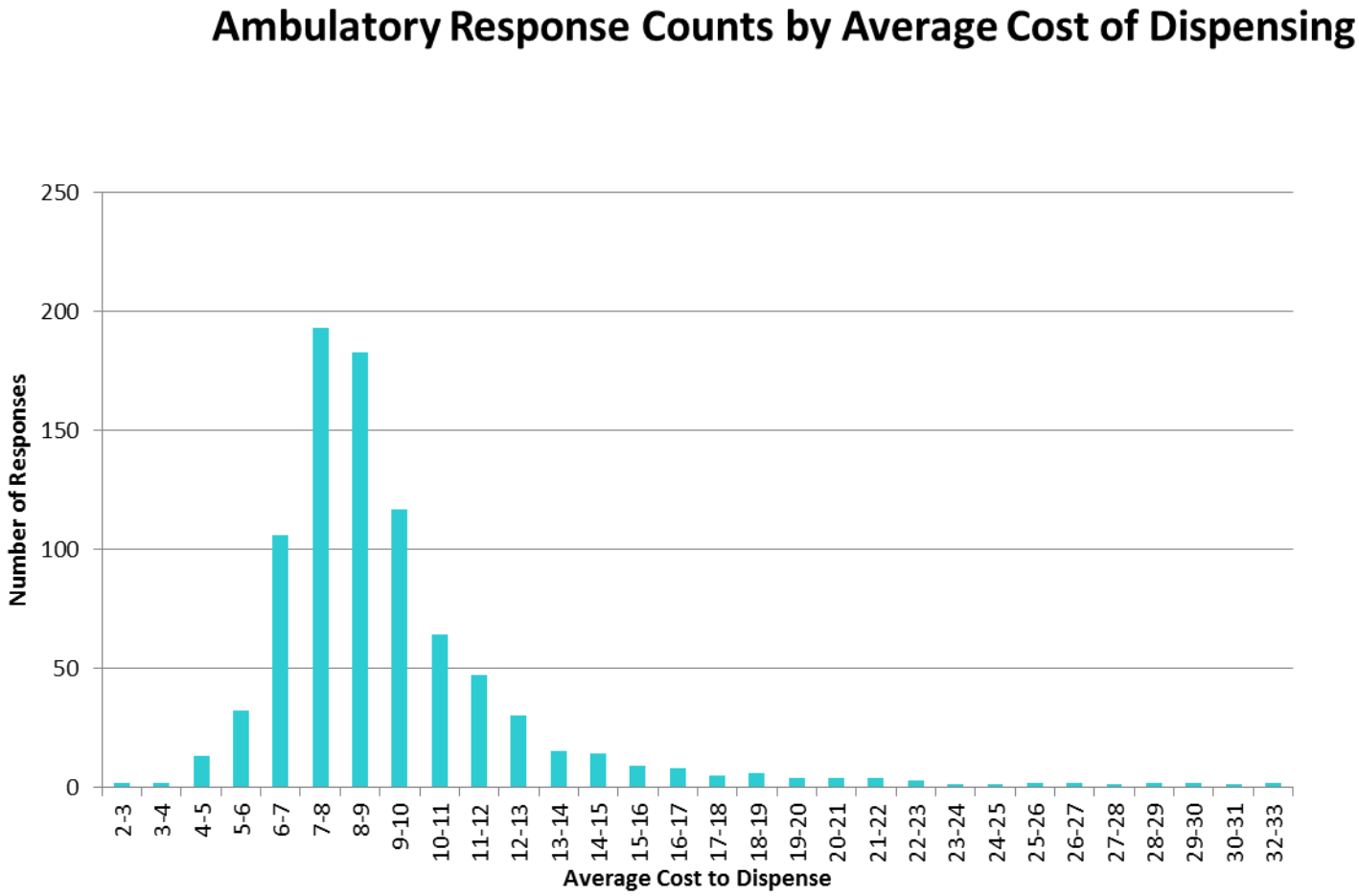
# Cost of Dispensing Survey
## Statistical Analysis Methodology




Winsorized average Cost Weighted by Response Probability

# Cost of Dispensing Survey

## Ambulatory Results

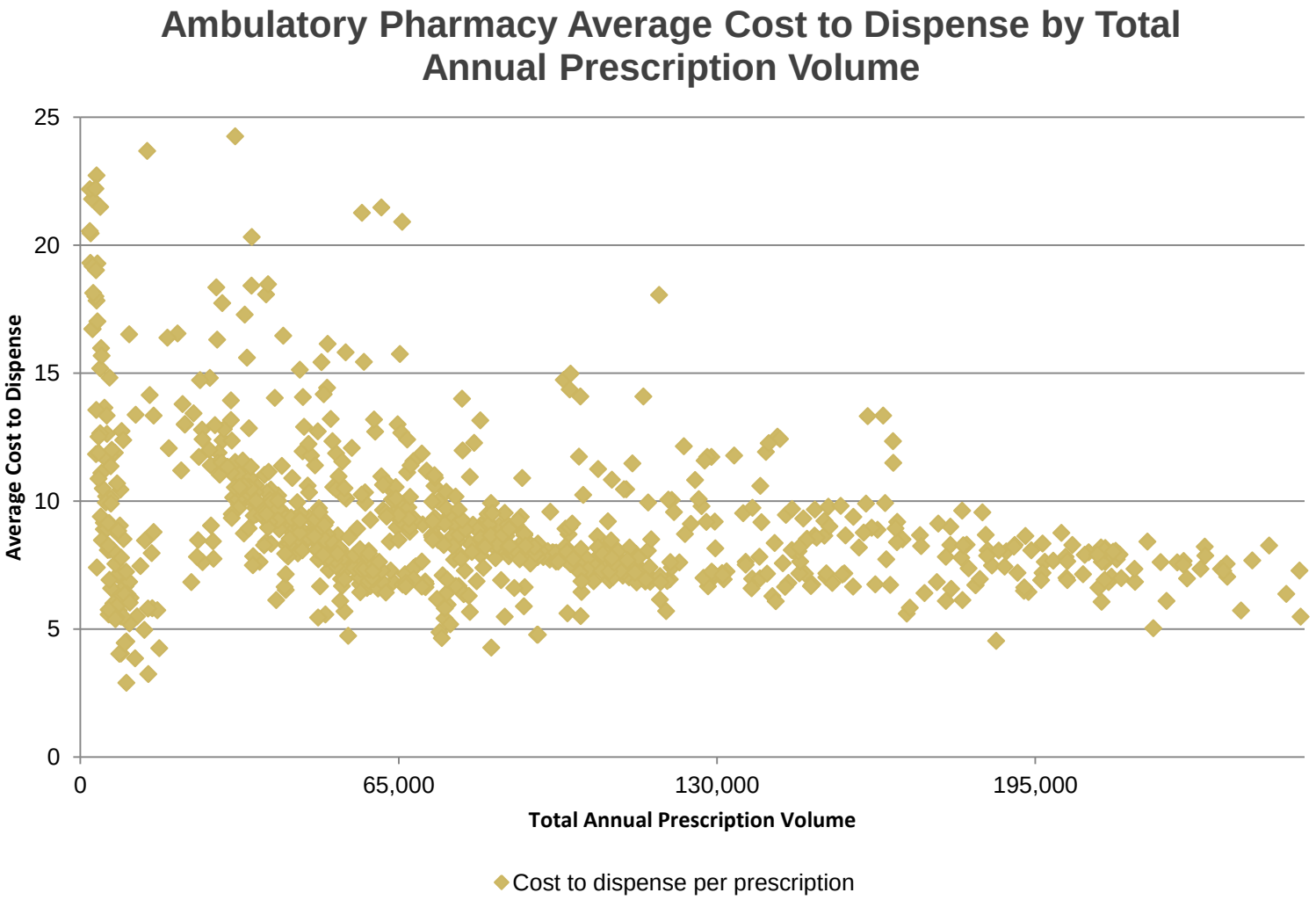


# Cost of Dispensing Survey
## Ambulatory Averages

| Annual Prescription Volume | n | N | Response Probability | Total Prescription Volume | Medicaid Prescription Volume | Margin of Error |
|---|---|---|---|---|---|---|
| 0–64,999 | 414 | 787 | $10.09 | $9.61 | $9.18 | $0.30 |
| 65,000 or more | 461 | 876 | $8.33 | $8.18 | $8.62 | $0.16 |
| All Tiers | 875 | 1,663 | $9.16 | $8.46 | $8.87 | $0.18 |

# Cost of Dispensing Survey

## Ambulatory Results



# Cost of Dispensing Survey

## 340B Results

| Annual Prescription Volume | n | N | Response Probability | Total Prescription Volume | Medicaid Prescription Volume | Margin of Error |
|---|---|---|---|---|---|---|
| All Tiers | 9 | 22 | $15.40 | $16.08 | $16.90 | $6.59 |

# Cost of Dispensing Survey

## Long Term Care Results

| Annual Prescription Volume | n | N | Response Probability | Total Prescription Volume | Medicaid Prescription Volume | Margin of Error |
|---|---|---|---|---|---|---|
| All Tiers | 20 | 52 | $12.15 | $8.95 | $7.18 | $3.22 |

# Cost of Dispensing Survey
## Blood Factor

- Survey data collected had a high degree of variability.
- Blood factor drugs are classified as Hemophilia beginning on page 2 of the Specialty Pharmaceutical Pricing List, found here: https://tenncare.magellanhealth.com/static/docs/MAC_Specialty_Pricing/TennCare_Specialty_Pharmaceutical_Pricing_List.pdf .

| Category | n | N | Response Probability | Total Prescription Volume | Medicaid Prescription Volume | Margin of Error |
|---|---|---|---|---|---|---|
| Blood Factor | 10 | 13 | $153.54 | $139.77 | $134.60 | $57.20 |

# Cost of Dispensing Survey
## Specialty (Non-Factor)

- Incomplete and insufficient sample submission for true Specialty Pharmacies resulted in high degree of variability and inconsistency
  - 8 of 16 pharmacies reporting did not meet TennCare's specialty pharmacy provider definition
  - Only 1 of 8 specialty pharmacies located in Tennessee
- Specialty drug reimbursement is not included in the CMS AAC definition if they are distributed primarily through the mail and not by a retail community pharmacy.
- Using the low volume tiered rate ($10.09) with a WAC discount ingredient cost is common in other states
- CMS has signaled they would likely accept this reimbursement methodology

# Cost of Dispensing Survey
## Summary

- TennCare to provide pharmacies with final guidance before April 1 pending ongoing conversations with CMS
- TennCare to use the following proposed Professional Dispensing Fees

| Pharmacy Type | Recommended Professional Dispensing Fee |
|---|---|
| Ambulatory with Volume of 0–64,999 | $10.09 |
| Ambulatory with Volume of 65,000 or more | $8.33 |
| 340B | $15.40 |
| LTC | $12.15 |
| Blood Factor | $153.54 |
| Specialty | $10.09 |
| Compounding | Level 1 rate of $10.00 or $10.09, no change to Level 2 or Level 3 |

# Cost of Dispensing Survey
## Other Considerations

- Compounding reimbursement will not change, except Level 1 will be reimbursed at $10.00 for high volume pharmacies and $10.09 low volume pharmacies.
- Tier Implementation: Ambulatory tier assignment will be based on volume reported by each pharmacy in the Cost of Dispensing survey, and TennCare will notify pharmacies in writing with their individual Professional Dispensing Fee prior to April 1
  - Pharmacy chains will be assigned a single PDF, based on the average volume per location
  - Policy decisions around new pharmacies, pharmacies with new ownership, or pharmacies who did not complete the survey will be forth coming pending discussions with CMS
  - TennCare annual attestation and repeat PDF survey process still to be determined
- OTC's will be priced with same algorithm as legend, prescription drugs pursuant to a prescription written by a Tennessee Medicaid prescribing provider.
  - OTC coverage will change and final guidance will be provided to pharmacies prior to April 1 by TennCare pending final CMS guidance

# Cost of Dispensing Survey
## Contact Information

**PDF Survey Questions**

- Mercer contact:

Scott Banken, CPA
612-642-8722
RxPDFS@mercer.com

- TennCare contact:

Raymond McIntire, D.Ph.
(615) 507-6497
Raymond.Mcintire@tn.gov

# QUESTIONS?

- Use the chat box function to submit your question.
- Identify your full name and pharmacy/organization you represent when submitting a question.

A recording of the Webinar will be posted to the MSLC Website at:

**http://www.mslc.com/Tennessee**


THANK YOU