MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

Recommendations for the Development of a New Fee-For-Service Drug Pricing/Pharmacy Reimbursement Methodology for the Texas Health and Human Services Commission

May 2014

Executive Summary

Introduction

Under contract to the Texas Health and Human Services Commission (HHSC), Myers and Stauffer LC assisted with the development of a new drug pricing reimbursement methodology to replace its current pharmacy pricing methodology. This analysis included both an evaluation of options for an ingredient reimbursement methodology and a study of pharmacy dispensing cost. This report includes information regarding the methodology and findings of the ingredient reimbursement analysis. A separate report from Myers and Stauffer includes the findings from the pharmacy cost of dispensing survey.

The pharmacy drug acquisition cost collection utilized the methodology and survey tool similar to those used by Myers and Stauffer for Medicaid pharmacy engagements in several other states. Invoices from third parties, such as wholesalers, which document drug purchase histories were collected and average drug prices for Texas Medicaid-participating pharmacies were calculated.

Myers and Stauffer obtained a list of pharmacy providers currently enrolled in the Texas Medicaid pharmacy program from the HHSC. According to the provider list, there were 4,433 pharmacy providers enrolled in the program that were located within the state of Texas. Myers and Stauffer used a random sampling approach to develop a sample of 2,000 pharmacy providers which were to be included in the pharmacy drug ingredient cost survey. These 2,000 pharmacies were requested to submit copies of invoices documenting their drug purchases for a given time period.

Myers and Stauffer utilized the submitted drug acquisition cost data to calculate average drug costs. Pharmacy characteristics, such as urban and rural setting or pharmacy specialty, were used to further refine the average drug acquisition costs (TX AAC). These TX AACs were used to represent the average cost of drugs for Texas pharmacies. They were compared to current Texas Medicaid reimbursement and to the National Average Drug Acquisition Cost (NADAC), which is maintained by the Centers for Medicare & Medicaid Services (CMS).

Summary of Findings

TX AAC Compared to Current Reimbursement
The following table contains the results of the comparison between TX Retail Community AACs and current Texas Medicaid Reimbursement benchmarks.

Table A: Average Percent Differences between TX Retail Community AAC and Relative Pricing Benchmark

Pricing Benchmark		Simple Average Percent Difference		Average Percent Difference Weighted by Utilization	
		Brand	Generic	Brand	Generic
Benchmarks Utilized in Current Methodology	WHSE	19.56%	99.60%	4.25%	(1.32%)
	DEAC	9.64%	81.52%	9.46%	(18.41%)
	WEAC	6.56%	10.89%	(1.18%)	(34.16%)
Additional Benchmarks	AWP	(18.29%)	(63.68%)	(17.90%)	(78.54%)
	WAC	(1.08%)	(25.49%)	(1.38%)	(39.07%)

*****Note: Positive percent values indicate TX Retail Community AAC is greater than the Pricing Benchmark. Negative percent values indicate TX Retail Community AAC is less than the Pricing Benchmark.

NADAC Compared to Current Reimbursement

The following table contains the results of the comparison between TX Retail Community AACs and current Texas Medicaid Reimbursement benchmarks.

Table B: Average Percent Difference between NADAC and Relative Pricing Benchmark

Pricing Benchmark		Simple Average Percent Difference		Average Percent Difference Weighted by Utilization	
		Brand	Generic	Brand	Generic
Benchmarks Utilized in Current Methodology	WHSE	16.71%	85.31%	2.81%	(0.67%)
	DEAC	8.06%	392.91%	8.58%	(13.61%)
	WEAC	3.90%	(0.87%)	(2.18%)	(33.53%)
Additional Benchmarks	AWP	(19.22%)	(68.36%)	(18.72%)	(78.39%)
	WAC	(2.02%)	(35.39%)	(2.44%)	(38.46%)

*****Note: Positive percent values indicate NADAC is greater than the Pricing Benchmark. Negative percent values indicate NADAC is less than the Pricing Benchmark.

As evidenced in Tables A and B above, the NADAC bears a similar relationship to current Texas Medicaid reimbursement benchmarks as the TX Retail Community AACs. Based on the Average Percent Difference Weighted by Utilization in both tables, drug ingredient reimbursement based upon drug acquisition costs could result in fiscal savings for the HHSC.

NADAC Compared to TX Retail Community AAC
The following table contains the results of the comparison between NADAC and TX Retail Community AACs.

Table C: Texas Retail Community AAC Compared to NADAC

Products	NDC Count	Simple Average Percent Difference	Average Percent Difference Weighted by Utilization
Brand	1,781	1.6%	1.02%
Generic	11,272	19.4%	(0.99%)

*****Note: Positive percent values indicate TX Retail Community AAC is greater than NADAC. Negative percent values indicate TX Retail Community AAC is less than NADAC.

Based on the comparison of NADAC and Texas Retail Community AAC weighted by drug utilization, on average, the Texas Retail Community AAC is 1.02% greater than NADAC for brand drugs. The comparison of NADAC and Texas Retail Community AAC weighted by drug utilization for generic drugs showed Texas Retail Community AAC is 0.99% less than NADAC, on average.

The results presented in Tables A, B, and C supports the observation that NADAC closely approximates the average cost at which Texas pharmacies purchase drugs.

Comprehensiveness of NADAC
The majority of NDCs dispensed to Texas Medicaid patients had an associated NADAC rate (86.7%).

Recommendations

Based on the results of these analyses, we recommend that the State **adopt a reimbursement methodology using the NADAC** for drug ingredient reimbursement. This approach accomplishes the following goals for the HHSC:

- Allows the HHSC to be compliant with the CMS Proposed Rule as it relates to pharmacy ingredient reimbursement by utilizing AAC rates
- Eliminates the need to establish new internal rate setting processes or solicit drug pricing information from its participating pharmacies since NADAC is provided by and maintained by CMS
- Allows reimbursement to reflects current drug costs since NADAC is updated weekly
- Creates claims processing changes that are readily incorporated into current systems since NADAC is available through the Medicaid website and through various drug information compendia
- Offers AAC-based reimbursement for the large majority of Texas Medicaid pharmacy claims
- Provides transparent drug reimbursement rates that are resistant to manipulation and provides the HHSC with valuable information on the prices at which pharmacies purchase drugs
- Results in opportunity for fiscal savings for drug ingredient reimbursement compared to current reimbursement
- NADAC rates are similar to Texas-specific average drug costs

With regards to reimbursement for drugs without NADAC rates, we recommend that the State **adopt a reimbursement methodology using WAC - 2% for brand drugs and WAC - 2% for generic drugs**. While NADAC and WAC - 2% would account for the majority of drug claims, a small number of drugs will not have either rate. For these drugs, we recommend that the State **adopt an edit to pause a claim at the Point-of-Sale and instruct pharmacies to call a help desk to establish an AAC rate.**

With regards to the Federal Upper Limits (FULs), we recommend that the State **adopt a policy to exclude AMP-based FULs from claim reimbursement.** In addition to these recommended changes to the drug ingredient reimbursement methodology, dispensing fee will need to be evaluated and addressed. We recommend that the State **adopt a dispensing fee of $8.98 for pharmacy claims.**

Objective

The Texas Health and Human Services Commission (HHSC) contracted Myers and Stauffer LC (MSLC), a national certified public accounting firm to assist with the development of a new drug pricing reimbursement methodology to replace its current pharmacy pricing methodology. In order to comply with new proposed federal requirements, the new drug pricing reimbursement methodology should utilize an Average Acquisition Cost (AAC) pricing benchmark.

AAC benchmarks include the option for a state specific or national acquisition benchmark. A state specific benchmark could be a pricing file operated by the HHSC that would be based upon average acquisition costs for covered products from a semi-annual survey of Texas retail community providers. Alternatively, the National Average Drug Acquisition Cost (NADAC) is a pricing reference file published weekly by the Centers for Medicare & Medicaid Services (CMS) that is based upon average actual acquisition costs of covered outpatient drugs collected from a monthly survey of retail community pharmacies across the United States.

The HHSC engaged MSLC to conduct a drug ingredient acquisition cost survey of Texas Medicaid providers. The results of this survey and their comparison to NADAC are outlined below. The HHSC also separately engaged MSLC to conduct a Cost of Dispensing (COD) fee study. The results of the COD study will be presented in a separate report.

Background

National application of AAC-based pharmacy reimbursement was championed by the National Association of Medicaid Directors (NAMD) in its white paper titled "Post AWP Pharmacy Pricing and Reimbursement" that was published in 2010, and authored by NAMD and the American Medicaid Pharmacy Administrators Association. Among the recommendations presented in the white paper was the establishment of a single national price benchmark for pharmacy reimbursement based on average drug acquisition costs. Such a benchmark would provide state Medicaid agencies with a more accurate and responsive pricing methodology for covered outpatient drugs since it would be based upon actual drug purchase experience. This approach to drug ingredient price determination not only provides greater accuracy and transparency in how drug prices are established, but it is also generally more resistant to manipulation. NAMD requested that CMS coordinate, develop, and support this benchmark. The Office of Inspector General (OIG) also provided a recommendation for CMS to "develop a national benchmark that accurately estimates acquisition cost and encourage States to consider it when determining Medicaid reimbursement for prescription drugs."[1]

CMS Proposed Medicaid Pharmacy Outpatient Rule (CMS-2345-P)

In its Proposed Medicaid Pharmacy Outpatient Rule (CMS-2345-P), published on February 2, 2012, CMS proposes to amend 42 CFR part 447, subpart I and to replace Estimated Acquisition Cost (EAC) with Actual Acquisition Cost as the basis for state Medicaid pharmacy ingredient cost reimbursement. Specifically, it states:

> *…we believe it is necessary for States to have a more accurate reference price to base reimbursement for prescription drugs. Therefore, we propose to replace the term, "estimated acquisition cost" with "actual acquisition cost" (AAC). We believe that changing this definition for the drug ingredient component of the reimbursement formula to AAC will be more reflective of actual prices paid, as opposed to estimates based on unreliable published compendia pricing...Therefore, in § 447.502, we propose to define actual acquisition cost as the agency's determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. (p. 5320-5321)*

In addition, CMS requires states to concurrently re-evaluate their dispensing fee when changing reimbursement for ingredient drug pricing from an estimated pricing methodology to one that is AAC-based. This is necessary to ensure the balance of overall pharmacy reimbursement. This regulatory change corresponds with the recommendation of the NAMD and the OIG discussed above, and is expected to become final in May 2014. In order to meet this requirement, Myers and Stauffer LC also assisted with a separate study to

[1] Department of Health and Human Services, Office of Inspector General. Replacing Average Wholesale Price: Medicaid Drug Payment Policy. OIG report no. OEI-03-11-00060. July 2011.

analyze the cost of dispensing prescriptions on behalf of HHSC, and has issued the results of this study in a separate report.

Development of National Average Drug Acquisition Cost (NADAC)

CMS contracted with Myers and Stauffer LC to conduct surveys of retail community pharmacy prices and to develop the NADAC pricing benchmark for drug ingredient reimbursement. The survey collects acquisition costs for covered outpatient drugs purchased by retail community pharmacies, which include invoice purchase prices from independent and chain retail community pharmacies. The invoice prices are used to calculate a NADAC rate for brand and generic products. The NADAC prices are updated and posted weekly on the CMS Medicaid website.

State Average Acquisition Cost Benchmarks

Prior to the development of the NADAC, several State Medicaid programs instituted their own state-level AAC pharmacy reimbursement programs. Beginning with Alabama in 2008, these programs utilize an approach to collecting pharmacy acquisition costs through surveys of in-state Medicaid-participating providers. Each of these programs also modified their dispensing fees to reflect the results of a cost of dispensing survey. The new dispensing fee was implemented simultaneously with the change in drug ingredient reimbursement.

Current Texas Reimbursement Policy

HHSC currently utilizes a pharmacy reimbursement methodology that is based upon published compendia pricing, pricing reported by manufacturers, and pricing reported by pharmacy warehouses. HHSC also incorporates the Federal Upper Limit (FUL) and State Maximum Allowable Cost (SMAC) rates into its reimbursement methodology. The current dispensing fee is based upon a fixed component of $6.50 plus a variable component based upon the drug ingredient reimbursement.

Scope

In order to evaluate the replacement of the current Texas Medicaid reimbursement methodology with an AAC-based pharmacy reimbursement formula, it is necessary to perform comparisons of current and potential reimbursement options. Potential reimbursement options considered in this analysis include average drug costs from Texas pharmacies and the NADAC. The NADAC is based upon a nationwide survey of pharmacies whereas a Texas AAC would be based upon surveys of pharmacies located in Texas. In addition, Myers and Stauffer LC will provide technical considerations for HHSC with regards to the adoption of NADAC for reimbursement.

Texas Ingredient Acquisition Cost Survey

Texas Pharmacy Provider Population

To obtain pharmacy drug acquisition costs, MSLC surveyed Texas pharmacies and requested copies of their invoices documenting purchases of drug products. HHSC provided MSLC with a list of active Texas Medicaid Providers with paid pharmacy claims within the previous six months. The provider attributes, such as provider locations and affiliations are summarized in the tables below.

Table 1: Provider Location Type

Attribute	Provider Count	Percent of Total
Urban	3,639	82%
Rural	794	18%
Total	4,433	100%

Table 2: Provider Affiliation Type

Affiliation	Provider Count	Percent of Total
Chain	2,921	66%
Independent	1,512	34%
Total	4,433	100%

Texas Pharmacy Survey Sample

From the list of 4,433 providers, MSLC choose a random sample of 2,000 providers that was representative to the universe of Texas pharmacy providers. The 2,000 providers were then surveyed for both the Cost of Dispensing and Ingredient Acquisition Cost Survey.

Table 3 below summarizes the provider attributes of the sampled providers differentiated by those who submitted data and those who did not submit data.

Table 3: Provider Survey Responses

	Providers who Submitted Data		Providers who did not Submit Data		Total
Overall	1,523	76%	477	24%	2,000
Number of Urban Providers	1,240	81%	380	80%	1,620
Number of Rural Providers	283	19%	97	20%	380
Number of Chain Providers	1,132	74%	188	39%	1,320
Number of Independent Providers	391	26%	289	61%	680

Survey Response by Provider Type

The HHSC was interested in obtaining acquisition cost across different provider types. Table 4 below summarizes the surveyed provider types differentiated by those who submitted data and those who did not submit data.

Table 4: Provider Types and Responses

Provider Type	Providers who Submitted Data		Providers who did not Submit Data		Total
Retail	1,370	77%	408	23%	1,778
340B	42	74%	15	26%	57
Specialty	33	66%	17	34%	50
Oncology	34	85%	6	15%	40
LTC	44	57%	31	43%	75
Total	1,523	**76%**	477	24%	2,000

Acquisition Cost Review

Collected Acquisition Cost

All submitted acquisition costs were imported into an electronic database for a series of programmatic quality assurance checks. These checks included but were not limited to the following:

- The submitted acquisition cost was for active and valid NDCs
- The acquisition cost received was from a surveyed Texas provider
- The submitted acquisition cost reflected the requested reporting month (September 2013)
- The submitted acquisition cost was not equal to or greater than Average Wholesale Price (AWP)

Methodology

The acquisition costs were grouped together by drugs with the same active ingredient(s), strength, dosage form, and route of administration. Within each grouping, unit costs that were greater than two standard deviations from the mean unit cost were removed. Additionally, a manual drug-by-drug review was performed by a team of pharmacist, accountants and analysts to remove any remaining outlier acquisition costs. Finally, an evaluation of factors that could influence drug pricing was performed (i.e.: drug shortages, manufacturer price changes).

Texas Average Acquisition Cost (TX AAC)

Provider Type Average Acquisition Cost (AAC) Rates

MSLC analyzed and calculated brand and generic TX AAC rates for study purposes. The number of TX AACs for each pharmacy provider type is listed in Table 5 below.

Table 5: Drug Groups with Collected Acquisition Cost Information Per Provider Type

	Retail Community	LTC	Specialty	Oncology
Number of Brand Rates	1,605	509	208	140
Number of Generic Rates	1,971	1,270	316	386
Total Rates	3,576	1,779	524	526

Comparison of Retail Community TX AAC to Relative Provider Types' AAC

Utilizing the TX AAC rates calculated in Table 5, MSLC compared the AAC of Retail Community providers to the AAC rates for the other three provider types: Long Term Care (LTC), Specialty and Oncology. Comparisons could only occur when there was sufficient acquisition cost data collected for the same drug group from both the retail community and the comparator provider type. The analyses were separated into brand and generic comparisons.

Brand Drug Groups

In the aggregate, the TX Retail Community AAC was greater than the comparator provider types' average acquisition cost. For example, the average percent difference between the TX Retail Community AAC and the LTC AAC was (3.44%). Thus, on average, the LTC average acquisition costs were 3.44% lower than the Retail Community TX AACs.

Table 6: Comparison of TX AACs by Pharmacy Type: Brand Drugs

	LTC	Specialty	Oncology
Drug Groups with both TX Retail AAC and Comparator Provider Type AAC	496	137	124
Average Percent Difference (TX Retail AAC and Relative Provider Type AAC)	**(3.44%)**	**(1.65%)**	**(1.62%)**

Generic Drug Groups
The same analysis was performed for generic drug groups and is illustrated in Table 7 below.

Table 7: Comparison of TX AACs by Pharmacy Type: Generic Drugs

	LTC	Specialty	Oncology
Drug Groups with both TX Retail AAC and Comparator Provider Type AAC	1240	273	377
Average Percent Difference (TX Retail AAC and Relative Provider Type AAC)	**(3.68%)**	**(9.62%)**	**(7.07%)**

Similar to brand drugs, the TX Retail Community AACs were slightly above the calculated average acquisition cost of the comparator provider types.

Comparison to Current Reimbursement
HHSC currently reimburses providers the lower of Usual & Customary charges, Gross Amount Due, and Estimated Acquisition Cost (EAC). In HHSC's current system, the submitted basis of cost (BOC) from the provider indicates what pricing indices will be utilized in the EAC calculation for ingredient reimbursement. EAC is defined using the following pricing indices:

- Direct Estimated Acquisition Cost (DEAC)
- Warehouse Cost or Direct Price to Chain Provider (WHSE)
- Maximum Allowable Cost (MAC)
- Wholesale Estimated Acquisition Cost (WEAC)

Table 8 below compares the average acquisition cost collected from Retail Community providers with the pricing indices noted above. The average percent difference per NDC was calculated, and then the calculated percent difference for each product was averaged for all products. On average, the TX Retail Community AAC is less than the WHSE, DEAC, WEAC, AWP, and WAC pricing benchmark for generic drugs. On average, the TX Retail Community AAC is less than the WEAC, AWP, and WAC for brand products, and greater than WHSE and DEAC.

Table 8: Average Percent Difference between TX Retail Community AAC and Relative Pricing Benchmark

Pricing Benchmark		Simple Average Percent Difference		Average Percent Difference Weighted by Utilization	
		Brand	Generic	Brand	Generic
Benchmarks Utilized in Current Methodology	WHSE	19.56%	99.60%	4.25%	(1.32%)
	DEAC	9.64%	81.52%	9.46%	(18.41%)
	WEAC	6.56%	10.89%	(1.18%)	(34.16%)
Additional Benchmarks	AWP	(18.29%)	(63.68%)	(17.90%)	(78.54%)
	WAC	(1.08%)	(25.49%)	(1.38%)	(39.07%)

National Average Drug Acquisition Cost

Development of National Average Drug Acquisition Cost (NADAC)

NADAC is another acquisition cost based reimbursement option for the HHSC to consider. CMS contracted with MSLC, a national certified public accounting firm, to conduct surveys of retail community pharmacy prices, and to develop the NADAC pricing benchmark based off drug ingredient costs. The survey collects acquisition costs for covered outpatient drugs purchased by retail community pharmacies, which include invoice purchase prices from independent and chain retail community pharmacies.

Comparison of NADAC to Relative Provider Types' AAC

MSLC compared the NADAC based upon Retail Community providers to the TX AAC rates for the other three provider types: Long Term Care (LTC), Specialty and Oncology. Comparisons could only occur when there was sufficient acquisition cost data collected for the same drug group from both the retail community and the comparator provider type. The analyses were separated into brand and generic comparisons.

Brand Drug Groups

On average, the NADAC was greater than the comparator provider types' average acquisition cost. For example, the average percent difference between the NADAC and the LTC AAC was (2.37%). Thus, on average, the LTC average acquisition costs were 2.37% lower than the NADACs.

Table 9: Comparison of NADAC with TX AACs by Pharmacy Type: Brand Drugs

	LTC	Specialty	Oncology
Drug Groups with both NADAC and Comparator Provider Type AAC	808	239	260
Average Percent Difference (NADAC and Relative Provider Type AAC)	**(2.37%)**	**(1.73%)**	**(0.74%)**

Generic Drug Groups
The same analysis was performed for generic drug groups and is illustrated in Table 10 below.

Table 10: Comparison of NADAC with TX AACs by Pharmacy Type: Generic Drugs

	LTC	Specialty	Oncology
Drug Groups with both NADAC and Comparator Provider Type AAC	12,177	3,911	5,526
Average Percent Difference (NADAC and Relative Provider Type AAC)	**5.37%**	**2.23%**	**8.66%**

Unlike with brand drugs, the NADAC rates were slightly below the calculated average acquisition cost of the comparator provider types.

NADAC as Compared to Current Reimbursement
Table 11 compares NADAC rates to the available pricing indices currently in use by HHSC. The average percent difference was calculated for each NDC, and then an aggregate percent difference was calculated for all products.

Table 11: Average Percent Difference between NADAC and Relative Pricing Benchmark

Pricing Benchmark		Simple Average Percent Difference		Average Percent Difference Weighted by Utilization	
		Brand	Generic	Brand	Generic
Benchmarks Utilized in Current Methodology	WHSE	16.71%	85.31%	2.81%	(0.67%)
	DEAC	8.06%	392.91%	8.58%	(13.61%)
	WEAC	3.90%	(0.87%)	(2.18%)	(33.53%)
Additional Benchmarks	AWP	(19.22%)	(68.36%)	(18.72%)	(78.39%)
	WAC	(2.02%)	(35.39%)	(2.44%)	(38.46%)

NADAC compared to Texas Retail Community AAC
The NADAC rates are calculated using invoices collected from all fifty states plus the District of Columbia. To evaluate the difference in the national average acquisition cost and the average acquisition cost of Texas providers, a comparison of the TX Retail Community AACs to the NADAC was performed.

The average percent difference for products that had both a TX Retail Community AAC and a NADAC benchmark was calculated. Additionally, the average percent difference was weighted by TX Medicaid utilization. This was done to minimize the impact of lowly utilized drugs. The results are illustrated in Table 12 below.

Table 12: Texas Retail Community AAC Compared to NADAC

Products	NDC Count	Simple Average Percent Difference	Average Percent Difference Weighted by Utilization
Brand	1,781	1.6%	1.02%
Generic	11,272	19.4%	(0.99%)

Based on the comparison of NADAC and Texas Retail Community AAC weighted by drug utilization, on average, the Texas Retail Community AAC is 1.02% greater than NADAC for brand drugs. The comparison of NADAC and Texas Retail Community AAC weighted by drug utilization for generic drugs showed Texas Retail Community AAC is 0.99% less than NADAC, on average.

Additional Drug Ingredient Considerations – Products with no NADAC Rates

Although there will be a NADAC rate for the large majority of a state's drug claims, not every drug will have a NADAC rate. Examples of drugs that might not have a NADAC rate at the time of a claim are new drugs, drugs dispensed primarily through a specialty pharmacy, and low utilized drugs. HHSC will need to develop an alternative pricing strategy for drugs without a NADAC rate.

When comparing availability of NADAC rates to historical Texas Medicaid drug utilization, the majority of NDCs dispensed to Texas Medicaid patients had an associated NADAC rate (86.7%). In cases where a NADAC rates is not available, many states that currently utilize AAC reimbursement use WAC-based rates to determine payment. While the use of WAC-based rates accounts for most of the drugs without a NADAC, there will be a minimal number of claims for drugs without a NADAC or WAC. In the cases where no NADAC or WAC rates are available, states may apply an edit to pause claims at the point of sale and request pharmacies to contact a help desk to submit invoice pricing to establish AAC rates. This process has worked well in several other states.

Consideration of AMP based FUL

With the finalization of the Affordable Care Act (ACA) Federal Upper Limit (FUL) Files, which is tentatively planned for July 2014, MSLC designed analyses to help the HHSC evaluate the potential impact of the draft ACA Average Manufacturer Price (AMP)-based FUL on modeled NADAC-based reimbursement fiscal analyses. Currently there is no official guidance from CMS as to which of the two draft ACA AMP-based FUL files should be utilized in pharmacy reimbursement by states. If HHSC chooses to exclude the FUL from reimbursement logic, they most likely would need to demonstrate that drug payment, in the aggregate, is below what the payment would have been if claims paid at the FUL. We examined each of the following available ACA AMP-based FUL files listed below:

- Draft Monthly ACA AMP-based FUL
- Draft Three-Month Rolling Average ACA AMP-based FUL

While still in draft form, other agencies have performed analysis on the potential impact of the AMP-based FULs. The U.S. Government Accountability Office (GAO) published a report on their findings comparing the ACA AMP-based FUL to the NADAC.[2] The GAO reported that nearly half of the ACA AMP-based FUL rates are lower than the corresponding NADAC rates within the sample tested. Likewise, nearly half of the FUL rates were higher than the corresponding NADAC rates. In its Informational Bulletin, CMS indicated "we expect that the use of the NADAC pricing could allow states to meet the FULs aggregate upper limit, and states may want to consider the use of the NADAC."

Comparison of NADAC and Draft ACA AMP-based FULs

Table 13 summarizes how the draft ACA AMP-based FULs compare to the NADAC rates. In order for an NDC to be included in these comparisons, there must have been both a NADAC and AMP-based FUL rate. There were instances when the FUL is greater than the NADAC. However, due to the lower of methodology, the lower NADAC rate would prevent payment at the FUL. For this reason, they were excluded from this analysis. However, when the FUL is lower than the NADAC, it would affect reimbursement so the analysis focused on those instances.

[2] United States Government Accountability Office. Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs. GAO report no. GAO-14-68. December 2013

Table 13: NADAC and AMP FUL Rate Comparison - Generic Products

	Percent of Instances were AMP FUL is less than NADAC	Average Percent Difference between NADAC and AMP FUL Weighted by Utilization
Monthly ACA AMP - Based FUL	45%	***31.99%***
Three - Month Rolling Average ACA AMP - Based FUL	44%	***33.72%***

Nearly 45% of the time, the AMP FUL is less than the NADAC. If the FULs are utilized in reimbursement, they will prevent providers from being paid at the NADAC. In these instances, the NADAC is roughly 30% greater than the FUL.

Consideration needs to be given to the inclusion or exclusion of AMP-based FUL rates in future pharmacy reimbursement, particularly with respect to meeting the FUL aggregate upper limit requirement. Since the FUL is less than the national average acquisition cost in many instances, MSLC modeled what the aggregate difference would be if the HHSC choose not to utilize them in pharmacy ingredient reimbursement. Estimated annual drug expenditures are compared for NDCs with a) utilization within a given month, b) an FUL rate on the monthly file, and c) either a corresponding NADAC or WAC rate. A year of claims were re-priced to calculate the expenditures if they were reimbursed using the FUL rate only, and also re-priced using the modeled NADAC-based reimbursement methodology. The twelve monthly results in the analysis were totaled to provide an annual aggregate difference as summarized in Table 14.

Table 14: Estimated Annual Expenditures: NADAC-based Reimbursement Methodology (State and Federal dollars)

FUL File	Estimated Expenditures if Reimbursed at FUL (a)	Estimated Expenditures if Reimbursed with NADAC-based Methodology (b)	Difference in Expenditures (Below FUL) (c = b – a)
Multi-Source Brand Drugs	*$11.04 M*	*$20.39 M*	*$9.35 M*
Generic Drugs	*$62.06 M*	*$41.72 M*	*($20.34 M)*
Draft Monthly ACA AMP FUL	**$73.10 M**	**$62.11 M**	**($10.99 M)**
Multi-Source Brand Drugs	*$8.67 M*	*$16.25 M*	*$7.58 M*
Generic Drugs	*$48.00 M*	*$33.14 M*	*($14.86 M)*
Draft Three Month Rolling Average ACA AMP FUL	**$56.67 M**	**$49.39 M**	**($7.28 M)**

Generic drug reimbursement would be below the FUL aggregate regardless of ACA AMP-based FUL file. The estimated results illustrate that HHSC would pay less than the FUL in the aggregate for generic products using a NADAC-based reimbursement methodology in which the FUL is excluded from the reimbursement logic.

Current multiple source brand drug reimbursement does not increase overall reimbursement above the FUL aggregate if ACA AMP-based FULs are not included in reimbursement. When the FUL is excluded in claims reimbursement, the amount of "over payment" for brand drugs is not enough to cause the aggregate payment to exceed the FUL. Please note that brand medically necessary (BMN) claims are excluded while preferred brand claims are included in an FUL aggregate analysis. Moving forward, ongoing review of preferred brand drug practices should be evaluated for drug groups with an applicable FUL value.

Recommendation

Based on the results of these analyses, we recommend that the State **adopt a reimbursement methodology using the NADAC** for drug ingredient reimbursement. First, this change would allow the HHSC to be compliant with the CMS Proposed Rule as it relates to pharmacy ingredient reimbursement by utilizing AAC rates. NADAC is maintained by CMS so the HHSC would not need to establish new internal rate setting processes nor solicit drug pricing information from its participating pharmacies. NADAC is updated weekly to reflect current drug costs. NADAC is available through the CMS Medicaid website and through various drug information compendia, therefore the HHSC can readily incorporate NADAC rates into its claims processing system. The large majority of Texas Medicaid pharmacy claims would have an associated NADAC rate so few claims would require an alternative pricing methodology. Further, NADAC rates do not differ materially from Texas specific average drug costs. Additionally, use of the NADAC results in an opportunity for fiscal savings as compared to the current reimbursement methodology. Finally, since the NADAC rates are based upon actual pharmacy invoices obtained from nationwide samples of pharmacies, NADAC is transparent, resistant to manipulation, and provides the HHSC with valuable information on the prices at which pharmacies purchase drugs.

From a fiscal standpoint, the Department would need to determine whether the net fiscal impact of this change, or other variations of the options discussed, will align with its pharmacy program goals and objectives. CMS appears to understand that States will need time to implement program changes so there does not appear to be feasibility issues due to timing of necessary claims system changes. The following section addresses considerations for NADAC implementation.

With regards to reimbursement for drugs without NADAC rates, we recommend that the State **adopt a reimbursement methodology using WAC - 2% for brand drugs and WAC - 2% for generic drugs**. The WAC shares a consistent relative relationship to the NADAC for brand drugs. Our analysis illustrated an average difference of 2% between WAC and NADAC for brand drugs. WAC does not bear a consistent relationship to generic drug costs.[3] However, to allow a majority of the claims without a NADAC to process without interruption, we recommend use of WAC - 2% until a NADAC is assigned. The 2% discount from WAC for generic drugs is recommended because it provides alternative reimbursement at the higher end of the range of generic drug NADAC to WAC comparisons while continuing to provide cost control. As presented earlier, most of a State's drug utilization will have assigned NADAC rates. Low utilized products and drugs that categorically would not have a NADAC rate, such as

[3] Department of Health and Human Services, Office of Inspector General. Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices. OIG report no. A-06-11-0002. October 2011.

new products and drugs not dispensed through the retail community pharmacy setting (such as some specialty drugs), will also be subject to reimbursement at WAC - 2%.

While NADAC and WAC - 2% would account for the majority of drug claims, a small number of drugs will not have either rate. For these drugs, we recommend that the State **adopt an edit to pause a claim at the Point-of-Sale and instruct pharmacies to call a help desk to establish an AAC rate.** This method is utilized by many states with AAC-based reimbursement rates. The key considerations to make are 1) ensuring a rate is established quickly, preferably within two hours, and 2) coordination between the claims processing vendor and help desk vendors is established to transmit AAC rates in a timely manner.

Due to the issues with the AMP-based FUL rates and the guidance by CMS that "the use of the NADAC pricing could allow states to meet the FULs aggregate upper limit,"[4] we recommend that the State **adopt a policy to exclude AMP-based FULs from claim reimbursement.** AMP-based FULs do not approximate Texas based AAC rates or the NADAC and therefore does not represent acquisition costs. Preliminary analysis shows that Texas would provide aggregate reimbursement below the FUL aggregate when utilizing the NADAC for reimbursement. AMP-based FULs are expected to become final in July 2014. By excluding AMP-based FULs from claim reimbursement, Texas would ensure that FUL rates that fall below the NADAC would not reimburse pharmacy providers below the average drug acquisition cost.

In addition to these recommended changes to the drug ingredient reimbursement methodology, dispensing fee will need to be evaluated and addressed. We recommend that the State **adopt a dispensing fee of $8.98 for pharmacy claims.** The single dispensing fee is the median dispensing fee weighted by Medicaid prescription volume as measured through the separate cost of dispensing study. Further detailed discussion regarding the dispensing fee is presented in the separate cost of dispensing survey report.

Recommended Reimbursement Methodology

Based upon our experience with State-level AAC programs and our knowledge of the NADAC program, our recommended reimbursement methodology for Texas Medicaid is as follows:

[4] CMCS Informational Bulletin. "Anticipated Finalization of Affordable Care Act Federal Upper Limits for Multiple Source Drugs." November 27, 2013.

Table 15: Proposed Reimbursement Methodology for Pharmacy Drug Ingredients

	When NADAC is available	When NADAC is unavailable	When NADAC and WAC are unavailable
Brand Drugs	Lower of: • NADAC + $8.98 Dispensing Fee • Usual and Customary Charge	Lower of: • WAC-2% + $8.98 Dispensing Fee • Usual and Customary Charge	Pharmacy prompted to contact State or vendor for submission of acquisition costs
Generic Drugs	Lower of: • NADAC + $8.98 Dispensing Fee • Usual and Customary Charge	Lower of: • WAC-2% + $8.98 Dispensing Fee • Usual and Customary Charge	Pharmacy prompted to contact State or vendor for submission of acquisition costs

*Note: CMS allows flexibility to meet the FUL in the aggregate. The final methodology for the ACA AMP-based FULs may impact the State's decision to include or exclude the FUL in claim adjudication.

Conclusion

Our recommendation is to move forward with the steps necessary to adopt NADAC for pharmacy reimbursement as discussed in the Recommendations section. The impending finalization of the proposed Outpatient Drug rule necessitates urgent planning for changes in pharmacy reimbursement policy.

We look forward to discussing this report with you and assisting you with your decision-making process regarding use of the NADAC for pharmacy reimbursement.

Appendix: Implementation of NADAC Reimbursement

Considerations for NADAC Reimbursement
HHSC will need to understand the considerations for utilizing the NADAC and prepare solutions for potential issues, as it will not be as simple as replacement of a pricing reference file. The following section outlines these considerations.

Understanding NADAC
It is imperative that HHSC understand what the NADAC will and will not provide as a drug pricing benchmark. The following is a brief list of characteristics of NADAC that will bring perspective to the use of this pricing benchmark.

Table 16: Considerations for NADAC Reimbursement

Topic	AWP	NADAC	Considerations for NADAC Reimbursement
Coverage of NDCs	All	-Approximately 87% of HHSC dispensed drugs -Limited to CMS covered outpatient drugs -Excludes some specialty drugs	Need alternative pricing methodology for claims for drugs without a NADAC rate
Comparison to current reimbursement	N/A	Reduced reimbursement	
Update frequency	Depends on manufacturer reporting	-Monthly brand and generic updates reflecting survey data -Weekly updates for brand NADACs reflecting changes in published pricing -Potential weekly updates due to help desk inquiries	NADAC has consistent reporting updates based upon drug pricing changes in the marketplace

Topic	AWP	NADAC	Considerations for NADAC Reimbursement
Backdating rate changes	Yes	-Yes for brand products to the extent that the NADAC effective date would be backdated to align with the change in published pricing effective date -No back dating for generic products	Changes in NADAC will not be backdated by CMS. If the State wants to allow NADAC rate changes to be backdated for providers to reprocess claims, it will need to make arrangements
Publication	Drug compendia	Drug compendia and Medicaid website	
Pricing Level	Unique per NDC	Unique per drug group. Drug group delineations are based upon drug ingredients, strength, dosage form, route of administration, OTC/prescription status, package size (for particular groups), brand/generic status, and labeler (for particular groups) NDCs within the same drug group will receive the same NADAC rate	NADAC rate assignment is similar to FUL and SMAC where NDCs from different labelers can share the same NADAC rate
Provider support	None	CMS NADAC help desk	NADAC help desk will not address individual claims, only address changes in drug prices that will appear on future NADAC rate files. HHSC will need to maintain a help desk to address individual claims and other state-specific issues
Reflective of drug acquisition costs	No	Yes	

For a more detailed explanation of the NADAC, CMS has provided a NADAC methodology document on its website (http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html).

NADAC file and claims payment system changes
The major drug compendia (including First DataBank, which HHSC utilizes) publish the NADAC rates obtained weekly from the CMS Medicaid website. However, by downloading the weekly NADAC file directly from the CMS Medicaid website, HHSC will be able to incorporate NADAC rate changes more quickly than would be available through drug compendia. HHSC will need to account for the time needed to program changes in the claims processing system. Although CMS has not indicated when they expect States to comply with the changes dictated in the Proposed Rule once it becomes final, the expectation is that CMS will allow some lag time for States to draft and submit State Plan Amendments and coordinate reimbursement system changes with their claims processors.

Policy Changes
As HHSC is aware, numerous process documents will need to be updated to reflect a change in reimbursement policy. This includes the Medicaid State Plan, State Rule(s), and provider manual.

NADAC Availability
The NADAC rates are currently available for use in reimbursement. Furthermore, it is expected that the Proposed Rule will become finalized in May 2014. Although CMS has not provided guidance with regards to a timeframe by which states will need to comply with the Final Rule, HHSC will need to consider what decisions will be required to comply with the changes in the CMS Rule.

Pricing for Specialty Drugs
The CMS Proposed Rule does not differentiate between specialty drugs and non-specialty drugs when changing EAC to AAC for ingredient cost. As discussed earlier, specialty drugs that are not dispensed through retail community pharmacies will not have a NADAC rate. Therefore, HHSC should consider how to provide reimbursement for specialty drugs in such a way that reimbursement is in compliance with the Rule. Our recommendation is to establish drug claims reimbursement rates for specialty drugs based upon drug acquisition costs collected from specialty pharmacies. A change in the ingredient reimbursement for specialty would also necessitate an evaluation of the dispensing fee. The Department would need to weigh its options for a change to its dispensing fee for specialty drug claims.

Stakeholder Involvement
A shift to an acquisition cost-based reimbursement is a substantial change in the reimbursement that pharmacies will receive. We recommend the incorporation of stakeholder communications beginning early in the process of changing pharmacy reimbursement. This outreach effort will help clarify the intent of HHSC, establish expectations with pharmacies on future reimbursement and provider support, and will be appreciated by the provider community.

Stakeholder outreach initiatives that have proven to be successful in other states include webinars/conference calls, provider bulletins, informational website with FAQ section, and local on-site presentations.

Provider Help Desk

CMS provides a help desk to support the NADAC, but the scope of services are limited to supporting questions with regards to the survey process and general understanding of the benchmark. It does not address concerns with individual claims.

As previously discussed, there will be covered outpatient drugs that will not have a NADAC rate. Therefore, HHSC will need to plan for addressing provider concerns with claims for drugs without an assigned NADAC. Even if the State decides to utilize a WAC-based reimbursement rate to produce reimbursement rates for drugs without a NADAC, there will still be drugs that do not have a reimbursement rate. Considerations that the State will need to make include:

- Is it acceptable to pause a claim from processing while the provider is directed to contact a help desk?
- Can the current claims processing help desk address this area of need or does the State need to consider hiring additional expertise?
- Does the State wish to backdate NADAC rate changes to allow providers to reprocess claims at the updated NADAC rate?

HHSC may need to consider contracting with a vendor to provide help desk services to support a NADAC-based reimbursement methodology. Our recommended scope of help desk services includes: addressing provider inquiries, performing research to validate drug price changes, establishing AAC reimbursement rates for drugs without a NADAC or WAC, transmitting rates to the claims processing contractor, and publishing AAC rates on a state-specific website.

NADAC Reimbursement Checklist

- ✓ Plan for stakeholder involvement in the planning stages of the reimbursement change
- ✓ Develop alternative reimbursement methodology for drugs without a NADAC
- ✓ Update results of previous cost of dispensing survey and select a dispensing fee to employ with the NADAC
- ✓ Finalize new reimbursement methodology
- ✓ Draft State Plan Amendment
- ✓ Ensure claims processing contractor has program changes in place and tested to apply new reimbursement methodology
- ✓ Obtain vendor to maintain help desk to address state-level claims for drugs without a rate and to handle provider issues with individual NADAC rates
- ✓ Ensure claims processing contractor and help desk vendor develop a communications plan prior to any reimbursement transition to send rates for drugs without NADACs for other alternative rates
- ✓ Obtain vendor to monitor whether HHSC reimbursement is at or below the FUL reimbursement in the aggregate