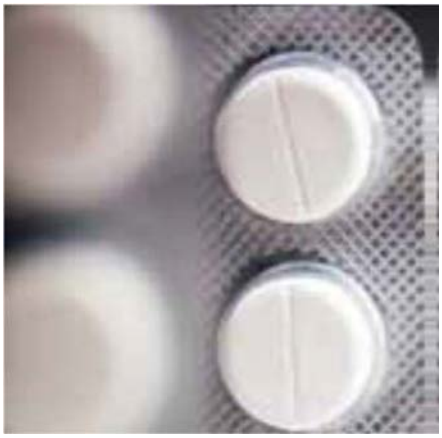

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

COST FEASIBILITY ANALYSIS OF NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) FOR USE IN MARYLAND MEDICAID PHARMACY REIMBURSEMENT

March 2017

Maryland Department of Health and Mental Hygiene
Cost Feasibility Analysis of NADAC
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Objective

The Maryland Department of Health and Mental Hygiene (DHMH) contracted Myers and Stauffer LC (MSLC) to study the feasibility and fiscal impact of incorporating the National Average Drug Acquisition Cost (NADAC) as the primary benchmark of its pharmacy pricing methodology. NADAC is a pricing benchmark published by the Centers for Medicare & Medicaid Services (CMS) that is based upon average acquisition costs (AAC) of covered outpatient drugs collected from monthly surveys of retail community pharmacies across the United States.

Due to the finalization of the CMS Covered Outpatient Drugs Rule (CMS-2345-FC), DHMH is required to update their fee-for-service (FFS) pharmacy reimbursement methodology to one that is based upon provider acquisition costs and a professional dispensing fee. An initial analysis was performed by MSLC in 2014; DHMH requested MSLC perform an updated analysis to estimate the fiscal impact of the new pharmacy reimbursement methodology due to the required changes in CMS-2345-FC.

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. Among the recommendations presented in the white paper was the establishment of a 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 reimbursement methodology for covered outpatient drugs since it would be based upon actual drug purchase experience. This approach to drug ingredient reimbursement determination would not only provide greater accuracy and transparency in how drug prices are established, but also would be 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]

To correspond with the recommendations of NAMD and the OIG, CMS contracted with MSLC in May of 2011 to develop and maintain the NADAC pricing benchmark. MSLC was already successfully calculating acquisition cost reimbursement rates for various state Medicaid agencies, so the NADAC expanded upon this rate setting methodology. The NADAC is calculated from invoices received through a voluntary nationwide survey of retail community pharmacies. The NADAC rates are updated on a monthly basis utilizing invoices from the most recent cost survey and are updated on a weekly basis due to changes in published pricing and help desk calls. CMS published the first draft NADAC files in October of 2012 and the final NADAC files were effective in November of 2013.

In February of 2012 CMS published its Covered Outpatient Drugs Proposed Rule (CMS-2345-P)[2]. The rule proposed to replace Estimated Acquisition Cost (EAC) with actual acquisition cost as the basis for State Medicaid pharmacy ingredient reimbursement. To ensure the overall balance of pharmacy reimbursement, CMS proposed that states concurrently re-evaluate dispensing fee reimbursement to reflect the cost of professional services provided. On February 1, 2016, CMS published the finalized Covered Outpatient Drugs Rule (CMS-2345-FC), with an effective date of April 2016. CMS re-emphasized the need to replace EAC with AAC as the basis for State

[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.
[2] Medicaid Program; Covered Outpatient Drugs; Final Rule, 42 C.F.R. §447 (2016). Retrieve at https://www.medicaid.gov/medicaid/prescription-drugs/covered-outpatient-drug-policy/index.html

Medicaid pharmacy ingredient cost reimbursement. Specifically, it states:

> *…We proposed to replace the term "estimated acquisition cost" (EAC) with "actual acquisition cost" (AAC) and to define AAC as the agency's determination of pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers (77 FR 5320 through 5359). As discussed in the proposed rule, we believe that this definition provides a more accurate estimate of the prices available in the marketplace, while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act. (p. 5174)*

On February 11, 2016, CMS sent a letter to all State Medicaid Directors indicating that states have until April 1, 2017 to revise their reimbursement methodology and submit a State Plan Amendment (SPA) to comply with the new provisions.[3] This letter highlighted various options, including NADAC, for states to consider as they seek to approximate actual acquisition cost for drug ingredient reimbursement.

Prior to the development and publication of the NADAC in 2013, several State Medicaid programs instituted their own state-level AAC pharmacy reimbursement programs, beginning with Alabama in 2010. These programs utilized an approach of collecting pharmacy acquisition costs through surveys of in-state Medicaid-participating providers. When implementing AAC as the basis for ingredient reimbursement, each of these programs simultaneously modified their dispensing fees. The updated dispensing fees reflect the professional costs to provide pharmacy services as illustrated through recent cost of dispensing surveys.

DHMH currently utilizes a pharmacy reimbursement methodology that is based upon published compendia pricing. Brand drugs are reimbursed utilizing the lower of Average Wholesale Price (AWP) minus 12%, Direct Price (DP) plus 8%, Wholesale Acquisition Cost (WAC) plus 8%, or the pharmacy's submitted charges. Generic drugs utilize the lower of the same reimbursement rates as brand drugs with the additional comparators of the State Maximum Allowable Cost (SMAC) rate and the Federal Upper Limit (FUL). The Department utilizes different dispensing fees based upon whether the drug is a non-preferred brand drug ($2.56 per claim) or generic drug or preferred brand ($3.51 per claim) or whether the recipient is resides in a nursing home ($3.51 for non-preferred brand drugs, $4.46 for generic drugs or preferred brand). Through this analysis, DHMH can reevaluate the fiscal impact and considerations of implementing a NADAC-based pharmacy ingredient reimbursement methodology with an enhanced professional dispensing fee in order to meet the recent changes in regulatory requirements from CMS.

Scope & Methodology

MSLC estimated the fiscal impact of DHMH updating its pharmacy reimbursement methodology to one that is based on AAC and a professional dispensing fee as required by CMS-2345-FC. To measure the fiscal impact of moving to AAC, MSLC repriced historical Maryland FFS pharmacy claims dispensed between November 1, 2015 and October 31, 2016 by comparing the paid amount of each claim to what would have been paid utilizing NADAC and a professional dispensing fee. Table 1 below provides a more detailed outline of the current and modeled reimbursement methodologies. Please note, the analysis incorporated the impact of both a change in ingredient and professional dispensing fee reimbursement methodologies in accordance with CMS-2345-FC.

[3] Department of Health and Human Services, Centers for Medicare & Medicaid Services. (2016, February 11) SMD: Implementation of the Covered Outpatient Drugs Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program. Retrieve at https://www.medicaid.gov/medicaid/prescription-drugs/covered-outpatient-drug-policy/index.html

Table 1: Reimbursement Methodologies

	Current Maryland FFS Pharmacy Reimbursement Methodology	Modeled NADAC-based FFS Pharmacy Reimbursement Methodology
Brand Drugs	*Lower of:* • EAC* • Usual and Customary Charges	*Lower of:* • NADAC. If no NADAC exists, then WAC+0%. • Usual and Customary Charges
Generic Drugs	*Lower of:* • EAC* • Maryland SMAC • FUL • Usual and Customary Charges	*Lower of:* • NADAC. If no NADAC exists, then the lower of: o WAC+0% o FUL • Usual and Customary Charges
Dispensing Fee	• $3.51 for brand products listed on the PDL and generic products. • $2.56 for brand products not listed on the PDL. • $4.46 for brand products listed on the PDL and generic products dispensed to nursing home facility recipients. • $3.51 for brand products not listed on the PDL dispensed to nursing home facility recipients.	• $10.49 for brand and generic products. • $11.49 for brand and generic products dispensed to nursing home facility recipients.

* EAC is the lower of AWP-12%, DP+8%, and WAC+8%

Observations & Findings

Fiscal Impact of NADAC Pricing Methodology

1. Ingredient Cost: Overall, replacement of Maryland's current pharmacy pricing methodology with NADAC would result in a decrease in annual spend on drug ingredient costs by an estimated $26.9M (State and Federal dollars).
2. Dispensing Fee: A corresponding change in the current dispensing fees listed above to $10.49 for all drugs and $11.49 for all drugs dispensed to nursing home facility recipients would result in an increase in annual spend by an estimated $27.8M (State and Federal dollars).
3. Net Fiscal Impact: The net annual fiscal impact with the modeled change to NADAC reimbursement is estimated **to increase annual spend by $0.9M** (State and Federal dollars).

Table 2: Estimated Fiscal Impact Results

	Current Estimated Expenditures (a)	Modeled Estimated Expenditures (b)	Estimated Fiscal Impact (c = b – a)
Ingredient Expenditures	*$523.4 M*	*$496.5 M*	*($26.9) M*
Dispense Fee Expenditures	*$14.6 M*	*$42.4 M*	*$27.8 M*
Net Fiscal Impact	**$538.0 M**	**$538.9 M**	**$0.9 M**

Assumptions and Limitations

Multiple assumptions were made in designing this analysis. The DHMH maintains a list of high cost products. Some of these products have a NADAC rate. The analysis was inclusive of these high cost products that have a NADAC rate and repriced accordingly. Additionally, the current State MAC rate was not used in the NADAC based reimbursement model since it was assumed that the NADAC would replace the State MAC rates. Submitted charges were excluded from the analysis due to the complexity involved with limited benefit. The analysis excluded NDCs for clotting factors, nutritional products, diabetic supplies (needles and syringes), and other non-drug products since there are not NADAC rates currently for these categories of products and many of these products do not have a WAC rate. Finally, due to their potential to adversely influence this analysis, claims for 340B drugs were excluded from this analysis.

Current DHMH reimbursement allows multi-source brand products to reimburse using the generic methodology unless the brand product is medically necessary to be dispensed as written or the brand product is dispensed as as brand preferred over generic. For purposes of this analysis we utilized this methodology and repriced all brand multisource claims at the generic NADAC rate if available unless the claim was submitted with a DAW 1 or 6. If a multi-source brand claims was submitted without a DAW 1 or 6 and there was no generic NADAC rate, the claim was repriced at the brand NADAC rate or in cases where there was no brand NADAC rate, WAC.

The original analysis performed in 2014 did not consider actual paid amounts associated with claims. Instead, actual units dispensed were repriced using the payment algorithms described in the Methodology section. For this updated analysis, the actual paid amount was compared with the calculated expected reimbursement under the new methodology using units dispensed.

The analysis utilized the most current, complete year of Maryland pharmacy claims data available (November 1, 2015 through October 31, 2016). Since this analysis looked at each claim, the pricing benchmarks for that day were used for repricing. On May 1, 2016, DHMH updated the FUL in their claims processing system to utilize the AMP-based ACA FUL. As a result claims with dates of service prior to May 1, 2016 were analyzed using the older FUL rates. Those with dates of service on or after May 1, 2016 utilized the new ACA FUL.

Conclusions

In CMS-2345-FC, CMS indicates that states will need to adopt a pharmacy reimbursement methodology based on acquisition costs. The NADAC, a national acquisition based pricing benchmark, represents a prime option for DHMH to transition from EAC-based reimbursement to an AAC based reimbursement methodology. CMS has indicated States will need to comply with the Rule by April 1, 2017. DHMH should be in compliance with the directives by adopting the NADAC and adjusting its professional dispensing fee to reflect the results of the cost of dispensing study.

The fiscal impact of changing reimbursement from the current pharmacy reimbursement methodology to a NADAC based methodology along with increasing the professional dispensing fee to $10.49 for brand and generic claims, and $11.49 for claims for nursing facility residents, results in an estimated annual net cost of approximately $0.9 M (State and Federal dollars).

There are multiple considerations the State will need to make in order to implement the NADAC for pharmacy ingredient reimbursement. For example, the State will need to consider how to address additional maintenance services, such as receiving and addressing pharmacy inquiries regarding individual claims, developing an alternative pricing strategy for drugs without a NADAC (such as specialty drugs, new drugs, or low utilized drugs), and assigning reimbursement rates for NDCs that are not identified on the NADAC rate file. Myers and Stauffer is assisting DHMH in accounting for these items.

Based on the results of these analyses, we conclude it is feasible for the Department to adopt a reimbursement methodology utilizing the NADAC. This change would allow DHMH to be compliant with the finalized CMS Covered Outpatient Drugs Rule without financially impacting pharmacy providers.