State of Vermont
Department of Vermont Health Access
280 State Drive – NOB 1 South
Waterbury, VT 05671-1010
dvha.vermont.gov

Agency of Human Services

Questions and Comments Related to the Pharmacy Reimbursement Changes Effective 4/1/2017

1) What is the NADAC?

The National Average Drug Acquisition Cost (NADAC) is a national reference benchmark that State Medicaid Programs may use when determining their reimbursement to pharmacy providers. It represents the national average invoice price derived from retail community pharmacies for drug products based on invoices from wholesalers and manufacturers. It does not reflect off-invoice discounts, rebates or price concessions.

2) What types of drugs are included on the NADAC file?

National Drug Codes (NDCs) and descriptions for prescription and non-prescription drug products are included on the NADAC file. The NDCs will be from labelers who are actively participating in the Medicaid Drug Rebate Program. The labeler's NDCs must be listed in the CMS Drug Data Reporting for Medicaid (DDR) system to be included in the NADAC file.

3) Will specialty drugs be included in the NADAC file?

In accordance with the definition of 'retail community pharmacy' as defined in section 2503, a) (4) of the Affordable Care Act, a retail community pharmacy does not include a pharmacy that dispenses prescription medications to patients primarily through the mail. Therefore, specialty drugs only available from specialty pharmacies who distribute these drugs primarily through the mail will not have a NADAC. Conversely, specialty drugs that are available from retail community pharmacies may have a NADAC, to the extent that cost observations are available for such drugs. Specialty drugs without a NADAC will be reimbursed at the lower of the benchmarks described in #7 below.

4) Will DVHA use the NADAC for both brand and generic drug products?
Yes, DVHA will use the NADAC whenever it is available, as the pricing benchmark for both brand and generic drug products.

5) Where can the NADAC file be found?

The updated NADAC file will be posted to the CMS Retail Price Survey website on a weekly basis in a Microsoft Excel format. The new file will be a full replacement file and the previous files are maintained on the website under "Archive Files". The NADAC pricing files are available through the following link: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html

6) What other documentation is available to assist with the NADAC file?

In addition to the NADAC rate files, NADAC data field definitions, webinar presentations and the NADAC methodology document, CMS will also publish a comprehensive week to week file comparison and associated data definitions that identify changes and general reasons for updates to existing NADAC rates. This comparison is intended to assist in identifying rate changes and provide the primary reason for the change. All NADAC related documents can be found on the CMS Retail Price Survey website located at: http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/survey-of-retail-prices.html

7) Will NADAC rates be available for all covered outpatient drugs?

The NADAC file currently contains rates for approximately 24,000 NDCs. Based on Vermont's utilization over the last six months of 2016, NADAC is available for 91% of our utilization based on volume.

8) CMS states that a NADAC price is not available for all drugs. What will Vermont use as a backup benchmark when a NADAC is not available?

DVHA will pay the lower of all the following benchmarks:

a. NADAC
b. The Wholesale Acquisition Cost (WAC) + 0%;
c. The State Maximum Allowable Cost (SMAC);
d. The Federal Upper Limit (FUL)
e. AWP-17%;
f. Submitted Ingredient Cost;
g. The provider's Usual and Customary (U&C) charges; or
h. The Gross Amount Due (GAD)

When NADAC is not available, one of the other benchmarks will be used, whichever is the lowest price.

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9) What will be the new Professional Dispensing Fee (PDF)?

The Department of Vermont Health Access (DVHA) conducted a dispensing fee survey of Medicaid-enrolled pharmacies to analyze the cost of dispensing prescription medications to Vermont Medicaid members.

Non-Specialty: Based on this survey, the new PDF for retail community pharmacies; institutional or long-term care pharmacies; and non-FQHC 340B pharmacies will be $11.13.

Specialty:
The professional dispensing fee for specialty pharmacies when dispensing specialty drugs will be $17.03. The survey results for costs of dispensing justified the creation of professional dispensing fees unique to specialty pharmacies.

10) How long will DVHA keep this new dispensing fee structure?

There is no predetermined duration identified with this new methodology. DVHA plans to conduct additional dispensing fee surveys at least once every 5 years.

11) Why were specialty pharmacies given a higher dispensing fee?

The survey results for costs of dispensing justified the creation of professional dispensing fees unique to specialty pharmacies.

The professional dispensing fee was calculated as the total related cost divided by the total number of prescriptions dispensed. The related cost were allocated based on the following ratio: area ratio, sales ratio, labor ratio, 100% pharmacy expense and non-pharmacy expense. The full methodology of the cost of dispensing process was described in the New England States Consortium Systems Organization report.

12) How will this impact drugs being billed under the 340B program?

Outpatient drugs being billed under the 340B program remains unchanged. For those entities whose 340B dispensing fees changed to $4.75 in July 2016, the new 340B dispensing fee will be $11.13.

13) What populations are affected:

All publicly-funded benefit programs including Medicaid. VPharm is largely unaffected since we do not "reprice" VPharm claims but simply pay the Part D cost-share. However, VPharm primary claims such as OTC's will be affected.

14) When will these changes be implemented?

Per the Covered Outpatient Drug Rule (CMS-2345-FC), the AAC and PDF reimbursement methodologies became effective on April 1, 2017.

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15) What is the anticipated net fiscal impact of the Professional Dispensing Fee (PDF) and Actual Acquisition Cost (AAC) implementation?

The overall budgetary impact of adopting the two-tier Professional Dispensing Fee for Community Pharmacies and Specialty Pharmacies, in combination with the new reimbursement methodology is projected to be an annual decrease in pharmacy reimbursement of $998,850 in SFY 18. This represents a 0.5% projected change in reimbursement.

16) How often is the NADAC file updated in the POS system?

The NADAC file is updated weekly by CMS and is therefore loaded into the POS weekly

17) How will the pricing change impact Medicaid-enrolled 340B pharmacies?

Non-FQHC Pharmacies whose previous dispensing fee was $4.75 (effective 7/1/16) will now receive $11.13 as their 340B dispensing fee effective 4/1/17. The reimbursement for FQHC's who submit 340B claims is not changing. Claims will be submitted in the same way and DVHA will reconcile on the back end using a $15 dispensing fee. Claims that are not 340B eligible will fall under the new pharmacy reimbursement formula.

18) How was the new "Professional Dispensing Fee" based on the February 8, 2017 cost of dispensing survey determined? Why was the "median" used and why has it not changed much since the last dispensing fee survey in 2006 which concluded that $10.50 was the cost of dispensing.

See #19 below, these two answers were combined.

19) The survey counted those of very low prescription volumes and highest prescription volumes. The large numbers of pharmacies dispensing over 200,000 prescriptions per year (they have the lowest "cost of dispensing") have a skewering effect on the number of small rural pharmacies that form the fragile healthcare network in

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Vermont. The lowest cost and the highest cost pharmacies should not have been counted. According to the survey the unweighted median = $12.56 and the weighted median = $11.30, however you are only willing to pay Vermont pharmacies $11.13, which is $.17 below the lowest survey results. Why is this?"

The measure of $11.13 is the median weighted by Vermont Medicaid volume for non-specialty pharmacies. The measure of $11.30 is the median weighted by Vermont Medicaid volume for all pharmacies, including specialty pharmacies.

By definition, the median weighted by Medicaid volume implies the point at which half of all Vermont Medicaid prescriptions (for pharmacies participating in the survey) were filled at that dispensing cost or less (and half of all Vermont Medicaid prescriptions were filled at that dispensing cost or more). This measurement is therefore the least "skewed" off any possible measurement to be used for determining an appropriate professional dispensing fee for Vermont Medicaid.

The survey results which Vermont relied upon were weighted according to the Vermont Medicaid prescription volume of each pharmacy that submitted a survey. For pharmacies that had Vermont Medicaid utilization (whether they were "high prescription volume" or "low prescriptions volume"), it was appropriate to include their cost of dispensing in the weighted median measurement.

Unweighted medians count each pharmacy equally, regardless of the impact of the pharmacy has on serving Vermont Medicaid beneficiaries. A weighted median (with Vermont Medicaid prescriptions as a weighting factor) provides a measurement that is more appropriate for the Vermont Medicaid program to use when determining an appropriate professional dispensing fee.

The professional dispensing fee was calculated as the total related cost divided by the total number of prescriptions dispensed. The related costs were allocated based on the following ratio: area ratio, sales ratio, labor ratio, 100% pharmacy expense and non-pharmacy expense. The full methodology of the cost of dispensing process was described in the New England States Consortium Systems Organization report.

20) What is the monthly date that Change Healthcare will update the CMS federal pricing source? Will the change in the ObamaCare affect this?

The NADAC file is updated weekly and the Federal Upper Limit files are updated monthly by CMS. Change Healthcare loads changes when they're made available by MediSpan. At this time, we don't know what changes if any will occur to the Affordable Care Act, so we are unable to assess any impact.

21) If we have a large price discrepancy or have to sell a very expensive medication below cost what is our recourse?

If it involves a state benchmark like MAC, the pharmacy can file a pricing appeal form with DVHA. This form is called the SMAC Research Request form, also known as the "Provider Pricing Appeal Form". States cannot change a NADAC listing. However, pharmacies can contact the NADAC help desk and request a rate review. They will be asked to submit an invoice. More information on the help desk process is available from CMS on their web site.
See: https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html

The NADAC Help Desk can be contacted through the following means.

Toll-free phone: (855) 457-5264
Electronic mail: info@mslcrps.com
Facsimile: (844) 860-0236

22) You are estimating an overall reduction of 0.5% in reimbursement to all pharmacies. I challenge your assumptions. Looking at last year's Medicaid total number of prescriptions and reimbursement we calculated that our pharmacy alone will have far less in payments from Vermont Medicaid. This reduction alone could destabilize many Vermont Pharmacies.

The following is a description of the analysis on the comparison of potential impacts between current and future reimbursement methodologies. The goal of the requested analysis was to estimate a difference between the sum of dispensing fees and ingredient costs generated by the current reimbursement methodology (based on AWP) and the sum of dispensing fees and ingredient costs generated by the future reimbursement methodology (based on NADAC). The analysis was based on Vermont paid claims with Rx dates of service for last 6 months - from August 1, 2016 through January 31, 2017. The analysis excluded claims on VMAP, Healthy Vermonters, Vpharm, Duals, and any other TPLs - but kept their OCC=3 claims.

The analysis took the current pricing data on AWP, SMAC, FUL, NADAC and WAC and applied them to the Total Units taken from the 6-month utilization data to model the

ingredient costs in the current and future reimbursement methodologies. To model the current and future dispensing fees, the analysis took the Total Number of Claims from the 6-month period and applied the current and future dispensing fee methodologies. Because not all NDCs have NADAC available, the analysis split all NDCs into three sub-reports: those drugs that had a NADAC and were priced using the NADAC; those that did not have a NADAC but had a WAC and were priced at WAC-0%; and those without a NADAC or a WAC which were priced at AWP-17%.

The analysis estimated the Total Ingredient Cost based on Current Reimbursement Methodology which is equal to the Total Units multiplied by the lower of EAC, SMAC and FUL. Then, the analysis estimated the Total Ingredient Cost based on Future Reimbursement Methodology, which is equal to the Total Units multiplied by the lower of NADAC, WAC+0%, AWP-17%, SMAC and FUL for NDCs depending on what pricing index was available (e.g. NADAC, WAC, or AWP).

The analysis estimated the Total Current Dispensing Fees which is equal to the Total Number of Claims for 6-month period multiplied by the Current Dispensing Fee of $4.75 for Regular drugs and $0.00 for Specialty drugs. Then, the analysis estimated the Scenario 1 Total Future Dispensing Fees equal to the Total Number of Claims for 6-month period multiplied by the Future Dispensing Fee ($11.13 for Retail and $17.03 for Specialty). The analysis additionally estimated the Scenario 2 Total Future Dispensing Fees equal to the Total Number of Claims for 6-month period multiplied by the Future Dispensing Fee ($11.13 for both Retail and Specialty).

Then, the analysis estimated the Payment based on the Current Reimbursement Methodology and Current Dispensing Fee. This was estimated as the Sum of Ingredient Costs based on Current Reimbursement Methodology plus Current Dispensing Fees of $4.75 for Regular drugs and $0.00 for Specialty drugs.

The analysis then estimated the future payment based on Future Reimbursement Methodology and Future Dispensing Fee. This was estimated as the Sum of Ingredient Costs based on Future Reimbursement Methodology plus Future Dispensing Fees ($11.13 for Retail and $17.03 for Specialty).

Finally, the analysis compared the current and future payments. The Summary tab showed the differences between the Payment based on the Current Reimbursement Methodology and Current Dispensing Fee versus the future payment based on Future Reimbursement Methodology and Future Dispensing Fee.

For the pharmacy referenced in #22 above, our analysis demonstrates that the sum of ingredient costs and dispensing fees will be 0.4% larger in the future because the sum based on the Future Reimbursement Methodology and Future Dispensing Fee will be slightly larger comparing to the sum based on the Current Reimbursement Methodology and Current Dispensing Fee.

23) The $.10 tax on every Medicaid prescription the State of Vermont must be declared null and void! This new pricing scheme invalidates the CMS waiver and must be stopped immediately.

The $0.10 tax (pharmacy assessment) referenced here, which started in 2005, is required by Vermont statute at 33 V.S.A. § 1955b. This new pricing methodology of reimbursing at Actual Acquisition Cost (AAC) is required by federal regulation as a result of the CMS Covered Outpatient Drug final rule (81 FR 5170). The implementation of AAC reimbursement does not invalidate the Global Commitment to Health 1115 waiver that CMS approved effective 1/1/17, nor does AAC reimbursement impact the pharmacy assessment in Vermont statute.

24) How does the Vermont Department of Health Access define the term "specialty pharmacy" within the context of the Medicaid prescription drug program?

The DVHA defines a specialty pharmacy as outlined by the Academy of Managed Care Pharmacy (AMCP) in a recent publication entitled *Format for Formulary Submission*, version 3.1 and the Specialty Pharmacy Association of America's definition below.

In addition to these industry definitions, DVHA will require any Specialty Pharmacy dispensing Specialty Drugs to DVHA members to be Certified by the Utilization Review Accreditation Commission (URAC) URAC, the Accreditation Commission for Health Care (ACHC), or the Center for Pharmacy Practice Accreditation (CPPA).

"Specialty pharmacies are distinct from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to efficiently deliver medications with specialized handling, storage, and distribution requirements with standardized processes that permit economies of scale. Specialty pharmacies are also designed to improve clinical and economic outcomes for patients with complex, often chronic and rare conditions, with close contact and management by clinicians. Health care professionals employed by specialty pharmacies provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs. Other support systems coordinate sharing of information among clinicians treating patients and help patients locate resources to provide financial assistance with out of pocket expenditures."

The Specialty Pharmacy Association of America defines a specialty pharmacy as follows:

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"Specialty pharmacy is a unique class of professional pharmacy practice that includes a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions. This unparalleled, patient-centric model is organized to dispense/distribute typically high cost, injectable/infusible/oral and other hard-to-manage therapies within a collaborative framework designed to achieve superior clinical, humanistic, and economic outcomes."

25) How does DVHA define the term "specialty drug" within the context of the Medicaid prescription drug program?

The DVHA uses the following guidelines to define a specialty drug provided the drug meets a minimum of (2) of the following requirements. The DVHA will be publishing on its website a complete list of drugs that DVHA considers specialty and limited to a specialty pharmacy no later than May 1st, 2017.

1.) The cost of the medication exceeds $5000 per month
2.) The medication is used in the treatment of a complex, chronic condition. This may include but is not limited to drugs which require administration, infusion, or injection by a health care professional.
3.) The manufacturer or FDA requires exclusive, restricted, or limited distribution. This includes medications which have REMS requirements requiring training, certifications, or ongoing monitoring for the drug to be distributed.
4.) The medication requires specialized handling, storage, or inventory reporting requirements.

The DVHA will be opening the Specialty Pharmacy network from BriovaRx to other Specialty Pharmacies on May 1st, 2017. We will be publishing a list of Specialty Drugs on the DVHA website that will be limited to Specialty Pharmacies who are certified as explained in #24 above. Some drugs now designated as Specialty will be opened to any retail pharmacy. More information on the Specialty Pharmacy changes will be forthcoming over the next few weeks.

26) In the Vermont Department of Health Access proposed Medicaid prescription drug reimbursement methodology, the Department defines AAC as the lower of 8 different formulas. Given that AAC is supposed to represent invoice cost and given that NADAC is invoice cost, shouldn't the proposed AAC methodology be revised as follows?

AAC is defined as NADAC, and if there is no NADAC for a given product, then AAC is defined as the lower of:

a. **The Wholesale Acquisition Cost (WAC) + 0% + PDF;**
b. **The State Maximum Allowable Cost (SMAC) + PDF;**
c. **The Federal Upper Limit (FUL) + PDF;**
d. **AWP - 17% + PDF;**
e. **Submitted Ingredient Cost + submitted dispensing fee;**
f. **The provider's Usual and Customary (U&C) charges; or**
g. **The Gross Amount Due (GAD)**

While NADAC will be the "lower of" for the majority of drugs, Change Healthcare has been able to demonstrate more current pricing in other states where it manages the NADAC. In these infrequent situations, this would be reflected as a State Maximum Allowable Cost (SMAC).

27) How do you define GAD, U and C, Submitted Ingredient Cost for purposes of the Medicaid Prescription Drug Program?

Gross Amount Due is defined by NCPDP as the total price claimed from all sources. For prescription claim request, field represents a sum of 'Ingredient Cost Submitted', 'Dispensing Fee Submitted', 'Flat Sales Tax Amount Submitted', 'Percentage Sales Tax Amount Submitted', 'Incentive Amount Submitted', 'Other Amount Claimed'. For service claim request, field represents a sum of 'Professional Services Fee Submitted', 'Flat Sales Tax Amount Submitted', 'Percentage Sales Tax Amount Submitted', 'Other Amount Claimed'.

Ingredient Cost Submitted is defined as Submitted product component cost of the dispensed prescription. This amount is included in the 'Gross Amount Due'

Usual and Customary Charge is defined as the amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed.