



**Methodology for Calculating the National
Average Drug Acquisition Cost (NADAC) for
Medicaid Covered Outpatient Drugs**

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Table of Contents

| | |
|-----------------------------------------------------------------|----|
| Background | 3 |
| Purpose | 5 |
| NADAC Reporting Level..... | 6 |
| Data Sources | 9 |
| Data Collection – Monthly Survey Process | 10 |
| Processing of Survey Data | 12 |
| National Average Drug Acquisition Cost (NADAC) Calculation..... | 14 |
| NADAC Updates | 20 |
| Deliverables | 24 |
| Quality Assurance | 30 |
| Help Desk Support Functions..... | 32 |
| Glossary | 33 |
| Appendix | 36 |

Background

Section 1927(f) of the Social Security Act provides, in part, that CMS may contract with a vendor to conduct monthly surveys with respect to prices for covered outpatient drugs dispensed by retail community pharmacies. In addition, section 1927(i) also provides in part that CMS complete an annual report to Congress that includes ingredient costs paid for single source, multiple source, and non-prescription covered outpatient drugs.

Monthly surveys focus on the drug prices that retail community pharmacies pay to acquire drugs. Specifically, the vendor surveys these acquisition costs of covered outpatient drugs purchased by independent and chain retail community pharmacies.

State Medicaid agencies reimburse participating pharmacy providers for covered outpatient drugs that are prescribed and dispensed to Medicaid beneficiaries. The payment consists of two parts: 1) reimbursement for drug ingredient costs, and 2) reimbursement for the cost of dispensing. In general, federal regulations require that Medicaid programs reimburse for drug ingredient costs at no more than the agency's best estimate of the acquisition cost for a drug. As defined in federal regulations at § 42 CFR 447.502, estimated acquisition cost (EAC) is the state's best estimate of the prices generally and currently paid by providers for a drug marketed or sold by manufacturers or labelers in the package size of the drug most frequently purchased by providers.

Many Medicaid agencies currently utilize published drug pricing benchmarks to determine the EAC for drug ingredient costs. The Average Wholesale Price (AWP) was a primary drug pricing benchmark utilized in pharmaceutical reimbursement by state Medicaid agencies. However, this benchmark has been the subject of much scrutiny and litigation over concerns that many AWP's were artificially inflated. The effect of artificially inflated AWP's results in an overstatement of EAC's and consequently the overpayment of the ingredient costs for drugs by state Medicaid agencies. Through numerous investigations, the Office of Inspector General found that AWP-based reimbursement was "fundamentally flawed" and caused Medicaid to pay too much for certain drugs.¹ Following the AWP litigation, a major publisher of pharmacy data discontinued its publication of AWP in September 2011. This heightened the need for an alternative data source for states to use when setting drug ingredient costs. Other published drug pricing benchmarks, such as Wholesale Acquisition Cost (WAC), Average Sales Price (ASP), and Direct Price (DP) are available for consideration, but each has limitations.

¹ Replacing Average Wholesale Price: Medicaid Drug Payment Policy. Office of Inspector General. July 2011. <http://www.oig.hhs.gov/oei/reports/oei-03-11-00060.pdf>

In late 2009, a working group within the National Association of State Medicaid Directors (NASMD) convened to discuss various alternatives to AWP. The working group authored a white paper in June 2010 entitled “Post AWP Pricing and Reimbursement” that evaluated and developed options for the replacement of AWP in Medicaid reimbursement methodologies. Among the recommendations presented in the white paper was the establishment of a single national pricing benchmark based on average drug acquisition costs. Such a benchmark would provide state Medicaid agencies with a better estimate of prices paid by pharmacies for drugs because it would be based upon actual drug purchases. This approach to drug ingredient price determination provides greater accuracy and transparency in how drug prices are established and is generally more resistant to manipulation. The NASMD requested that CMS coordinate, develop, and support this benchmark.

CMS contracted with Myers and Stauffer LC, a national certified public accounting firm, to conduct surveys of retail community pharmacy prices, including drug ingredient costs, and to develop the National Average Drug Acquisition Cost (NADAC) pricing benchmark. The NADAC survey process focuses on retail community pharmacy 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.

Included in the Survey of Retail Prices, in addition to a survey of the cost pharmacies incur to purchase drugs, CMS collects information on consumer prices for the purchase of drugs. This survey focuses on the collection of retail community pharmacy prices charged to consumers and the calculation of consumer unit drug prices. These unit drug prices, which represent the prices charged to consumers are reported as the National Average Retail Price (NARP). The NARP is comprised of a statistically weighted average of three types of consumers: cash paying consumers, commercial third-party insurance consumers, and Medicaid consumers. Each consumer type will have unit prices identified by their 11-digit National Drug Code (NDC). The methodology for calculating the NARP is presented in a separate document.

Purpose

The purpose of this document is to describe and illustrate the methodology utilized to calculate the NADAC for Medicaid covered outpatient drugs.

The NADAC is designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. States may want to consider the use of the NADAC. However, we note that a state must submit a state plan amendment in accordance with the state plan requirements if it decides to use NADACs as a basis for payment.

NADAC Reporting Level

The NADAC for prescription and over-the-counter covered outpatient drugs is reported at the 11-digit National Drug Code (NDC) level. The NADAC is calculated at the drug grouping, drug category, and pharmacy type level.

Drug grouping is primarily based on active ingredient(s), strength, dosage form, and route of administration. In most cases, NDCs for drugs that are pharmaceutically equivalent are assigned to the same drug group.

In some cases, additional parameters are included in defining a drug group. For example, package size is included as an additional delineation when there is a demonstrated variation in acquisition prices between package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing (e.g., topical creams and ointments). Please refer to the “NADAC Calculation” section for more details.

Drug category represents the classification of each NDC as one of the following: Single source (‘S’), Innovator multiple source (‘I’), or Non-innovator multiple source (‘N’). In general, NDCs designated as ‘S’ and ‘I’ are considered brand drugs and NDCs designated as ‘N’ are considered generic drugs for purposes of calculating the NADAC. Drug category designations are listed in the “Classification for Rate Setting” field in the NADAC reference file. The Drug Category is obtained from the most recent CMS covered outpatient drug product file.

Drug category overrides indicate when the CMS covered outpatient drug product file drug category, ‘S’, ‘I’, and ‘N’ has not been applied. The override indicator is to alert states that this S/I/N categorization was not followed during the NADAC calculation for the applicable NDCs. In light of this, the process to override the drug category is necessary to align with reimbursement designations used by states for these drugs. States will not be required to match the NADAC designations or to reconcile previous reimbursement to match overrides.

When utilizing the NADAC for reimbursement, state Medicaid programs have the flexibility to apply their own brand or generic designations when determining reimbursement for these drugs. States must submit a state plan amendment in accordance with state plan requirements if they decide to use NADACs as a basis for payment.

For example, authorized generic drugs are listed in the CMS covered outpatient drug product file as ‘I’ drugs as they were approved under a New Drug Application (NDA).

For NADAC calculations, authorized generic drugs are identified as generic drugs since they are generally designated as generic by most state Medicaid programs for the purposes of reimbursement.

Another example is proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA), and labeled 'N' in the CMS covered outpatient drug product file. For NADAC calculations, proprietary named drugs, approved under an ANDA are identified as brand drugs since they are generally marketed and priced as brand drugs. In this example, the NDC is identified with a 'B-ANDA' designation in the "Classification for Rate Setting" field of the NADAC reference file and, if available, both the brand and corresponding generic pricing are shown.

Pharmacy type is the classification of a pharmacy into categories. There is currently one type of pharmacy: retail community pharmacy as defined in section 1927(k) of the Social Security Act. For purposes of the NADAC, only chain and independent pharmacies have been surveyed.

Application of NADACs to Individual NDCs

The below example illustrates the application of NADACs to NDCs using the drug grouping, drug category and pharmacy type indicator. Only NDCs with the same drug grouping, drug category and pharmacy type indicator will share the same NADAC.

Example 1: Application of NADACs to Individual NDCs

| Drug Grouping | NDC | Drug Category | Pharmacy Type Indicator | NADAC |
|-----------------------------|---------------|---------------|-------------------------|---------|
| Lipitor 10mg tablet | xxxxx-xxxx-xx | S/I | C/I | 2.00000 |
| atorvastatin 10mg tablet | xxxxx-xxxx-xx | N | C/I | 1.00000 |
| Lipitor 20mg tablet | xxxxx-xxxx-xx | S/I | C/I | 4.00000 |
| atorvastatin 20mg tablet | xxxxx-xxxx-xx | N | C/I | 3.00000 |

Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for these drug groupings.

Drug Grouping: All NDCs for Lipitor and atorvastatin 10mg tablets are classified into one drug group since they contain the same combination of active ingredient, strength,

dosage form, and route of administration. However, when a NADAC is calculated for the applicable NDCs in the drug group, these NDCs are further delineated by drug category and pharmacy type. Likewise, the NDCs for Lipitor and atorvastatin 20mg tablets would be classified together into a drug group separate from the 10mg version, due to the different strengths (10mg versus 20mg).

Please note that a drug group is comprised of pharmaceutically equivalent products at the active ingredient, strength, dosage form and route of administration level. Oral dosage forms of tablets and capsules will not be separated by package size. A NADAC may be calculated for package sizes within a drug group when the drug form is 'ml' or 'gram'.

Drug Category: The drug category differentiates the 'S/I' NDCs and the 'N' NDCs. Among NDCs with the same drug grouping, NDCs with a drug category of 'S/I' will receive the brand NADAC and NDCs with a drug category of 'N' will receive the generic NADAC. This is illustrated in the example for Lipitor 10mg tablets and atorvastatin 10mg tablets having the same drug grouping but different drug categories and therefore different NADACs.

Pharmacy Type Indicator: The pharmacy type indicator of C/I signifies that the NADAC was based on drug acquisition costs from chain and independent pharmacies.

Data Sources

Numerous data sources are relied upon in order to facilitate the collection, calculation, analysis and reporting of the NADAC. Those data sources include:

- Drug acquisition cost data collected through voluntary monthly surveys of retail community pharmacy entities (independent and chain pharmacies). .
- A national pharmacy file used to identify individual pharmacies.
- Drug identification and published pricing information obtained from CMS and verified that NDCs meet NADAC criteria.
- The most recently available covered outpatient drug product file from CMS's Medicaid website, Medicaid.gov, to use in NADAC criteria evaluation. In addition, interim updates, when available, are received from CMS for newly available covered outpatient drugs.
- The most recently available CMS list of labelers that are in the Medicaid Drug Rebate file (MDR) from CMS's Medicaid website, Medicaid.gov, to use in NADAC criteria evaluation. In addition, weekly updates, when available, are received from CMS for new rebating labelers.

Data Collection – Monthly Survey Process

On a monthly basis, Myers and Stauffer LC will collect acquisition cost data from a random sample of pharmacies selected from all 50 states and the District of Columbia. Pharmacy entities surveyed include independent and chain retail community pharmacies in the United States. A national pharmacy compendia file containing information on retail pharmacies throughout the country is used to determine the pool of pharmacies eligible for each survey.

Independent and Chain Pharmacies - A random sample of independent and chain retail community pharmacies is generated each month. The sample is drawn from the total population of such pharmacies. The composition of the survey sample closely aligns with the composition of the pharmacy population with regards to general pharmacy characteristics (i.e., independent, chain, rural, and urban).

Specialty Pharmacies - Specialty pharmacies are excluded from the surveys at this time. Specialty pharmacies are identified by their classification as primarily specialty pharmacies in the National Council for Prescription Drug Programs (NCPDP) database. Furthermore, the Utilization Review Accreditation Commission (URAC) specialty pharmacy certification list is also used as a supplement to identify additional specialty pharmacies for exclusion from the surveys.

Survey Process – Prior to the first of each month, survey letters are mailed to the physical location address of each selected pharmacy. The survey letter requests the voluntary submission of drug acquisition cost data from the pharmacy's previous month of drug purchases. Pharmacies are asked to submit the requested information within two (2) weeks. Upon request from a pharmacy, survey letters can also be sent by electronic mail to the pharmacy or, in the case of chain providers, a corporate contact. Reminders are sent 10 to 14 days following the initial letter.

Survey Request – Pharmacies are requested to voluntarily submit invoices on all covered outpatient drug purchases made from all wholesalers or manufacturers during the specified time period. Information requested through the survey consists of a minimum of the following:

- NDC
- Unit Price Paid
- Invoice Date
- Quantity Purchased

The data items listed above are the only information collected from submitted documents that is used in calculating the NADAC. Other information from the survey submissions is not used for calculating the NADAC.

The information collected through the survey is information that is already contained in documentation maintained by a pharmacy; therefore, it is readily available and requires minimal effort to locate, identify and submit. The time needed to respond to the survey request should take no more than 30 minutes of non-pharmacist staff time. Moreover, many pharmacy inventory systems have functionality that allows them to easily and quickly produce and send a report that includes the requested survey information. Another option available to pharmacies is to contact their wholesalers and request that they produce and send the requested survey information on the pharmacy's behalf. Survey data is accepted in hard copy and electronic formats.

Pharmacy invoices that reflect drugs purchased through the 340B program are requested to be excluded from survey submissions. If invoices with 340B pricing are submitted and able to be identified they are excluded from the NADAC calculation. When pricing varies from a range of expected values, further research is done to determine if the pricing reflects 340B pricing including contacting the provider to confirm the type of acquisition prices being submitted. For purposes of this survey, discounts or rebates that are not reflected on the invoice at the drug line item level are not factored into the NADAC calculation.

In addition to information on drug purchases, pharmacies are requested to send back the cover sheet that accompanied the survey letter. This cover sheet indicates the pharmacy's intent that its submitted information remain confidential. If the cover sheet or other documentation requesting confidentiality is not included in the pharmacy's submission, Myers and Stauffer LC will contact the pharmacy to confirm its intent regarding the confidentiality of the submitted data. Regardless, please note that CMS is the owner of submitted data and Myers and Stauffer LC is contractually prohibited from releasing this data to any other parties. Refer to Appendix 3 of this document for a sample of the survey letter and cover sheet.

Processing of Survey Data

Acquisition cost data submitted for the survey is accepted in many formats. Pharmacies or their wholesalers can submit their acquisition costs in electronic format via electronic mail delivery, send hard copy duplicates via postal mail, or transmit submissions via facsimile.

As survey responses are received, several tasks are performed to process the submissions. Submissions are entered in a receipt log to ensure that survey responses are tracked and counted. Whether a pharmacy has marked its submission as confidential is tracked. In cases where the pharmacy has not indicated that data provided are confidential, Myers and Stauffer LC will contact the pharmacy to clarify whether this omission was intentional. If the pharmacy chooses to indicate that its submission is confidential, a note is made in the receipt log.

Survey data is reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Myers and Stauffer LC may contact pharmacies that submitted survey data to clarify questions about the submissions. Drug prices that are found to be equal to or greater than AWP are evaluated in accordance with the process described in the “Quality Assurance” section of this document and entered into the database only if they meet the criteria for inclusion in that section. Refer to the “Background” section of this document for further discussion on limitations with the AWP.

If required data (e.g. NDC information) is not submitted or does not pass one of the quality assurance checks (such as NDCs that do not match the NDC listed in the CMS Medicaid Drug Rebate file or acquisition cost outliers), the vendor deems the submission is to be excluded from consideration in the calculation of the NADAC. Universal Product Code (UPC) and Health Related Item (HRI) codes, to the extent that they can be, are converted to their corresponding 11-digit NDCs for purposes of the NADAC calculation.

Survey data received in electronic format is directly imported while data received in hard copy are manually entered into the database. Once the database is complete, quality assurance procedures are performed to ensure that data are accurately and completely entered. Such procedures include comparisons between the actual submitted documents and related database entries, and reconciliation between the number of data lines submitted electronically versus those entered into the database.

All submitted electronic and hard copy survey responses are stored in a secure and confidential manner. Hard copy files are stored in a locked environment until sent to CMS or destroyed upon CMS direction in accordance with federal records retention requirements. All information submitted is the property of CMS, and Myers and Stauffer LC is prohibited from utilizing this data for any purpose other than as directed by CMS.

National Average Drug Acquisition Cost (NADAC) Calculation

Prior to NADAC calculations, the data are grouped based on active ingredient(s), strength, dosage form, and route of administration. The data is also classified according to its drug category as either single source (S), innovator multiple source (I), or non-innovator multiple source (N).

In order to be included in the NADAC calculations, the data must satisfy the following criteria:

- Data must be from pharmacies surveyed in the month under review.
- Invoice dates must be from the month under review.
- Acquisition cost data must be for valid, active NDCs listed in published pricing compendia. Obsolete NDCs and CMS-terminated NDCs are excluded from NADAC calculations.
- Products must be on the latest CMS covered outpatient drug product file or a newly added drug determined by CMS to be a covered outpatient drug as defined by section 1927 of the Social Security Act.
- Products must not have a code that indicates the drug has been declared less than effective by the CMS Drug Product Efficacy Study and Implementation (DESI). Such drugs, identified as having a CMS DESI code of 5 or 6, are excluded. CMS DESI codes are obtained from the CMS covered outpatient drug product file.
- Only one cost observation (a price that appears on an invoice), for each pharmacy, for each NDC, is included in the NADAC calculation. If a pharmacy submits more than one cost observation for the same NDC during the month, the cost observation with the latest date of purchase is used. Use of acquisition cost for the latest date of purchase allows for drug price changes that occur during the month to be reflected in the costs that are used to calculate the NADAC. If a pharmacy submits more than one cost observation for the same NDC with the same purchase date, the lowest cost is used. The basis for the inclusion of the lower rate is that if a pharmacy makes multiple purchases of the same NDC on the same purchase date, then the pharmacy is able to acquire the drug at the lowest cost possible.

A minimum number of cost observations necessary to calculate a NADAC has not been established. The number of cost observations necessary to obtain estimates with reasonable precision depends on the overall variation of acquisition costs, with no less than five cost observations used for NADAC calculations where costs are closely aligned. A thorough review of each NADAC calculation is performed to ensure reliable rate calculations, appropriate removal of outlier costs, and other measures defined in the “Quality Assurance” section of this document.

The NADAC rate, defined by drug grouping, drug category, and pharmacy type is calculated as the average of the per unit cost observations. The NADAC is a simple average of the drug acquisition costs submitted by retail community pharmacies. NADACs are calculated as a single national average; regional price variations are not incorporated at this time as the relative impact on the NADAC calculation is minimal. Also, NADACs are not weighted based upon independent or chain pharmacy types as the relative impact of the differences in their respective acquisition costs are minimal.

The dispersion of drug prices is measured by the standard deviation. Cost observations greater than +/- two (2) standard deviations from the mean are removed as outliers. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining a large majority of cost observations used to calculate a mean. Other outlier removal processes have been examined by consulting statisticians. At this time, this approach is the most effective process for removing outliers.

Once outlier observations are removed, the average of the remaining per unit costs is calculated. A drug-by-drug review of the remaining cost observations is conducted by a review team comprised of pharmacists and analysts.

Separate NADACs are calculated for ‘S/I’ drugs and ‘N’ drugs. The NADAC for ‘S’ and ‘I’ products is referred to as brand drug NADACs. The NADAC for ‘N’ products is referred to as generic drug NADACs. Generally, there is one brand drug NADAC for ‘S’ and ‘I’ NDCs within a drug grouping. Likewise, one generic drug NADAC will apply to all ‘N’ NDCs within a drug grouping. This aligns with brand and generic reimbursement policies and requirements generally utilized by state Medicaid programs. For example, in accordance with their approved state plan, Medicaid programs may generally use a different reimbursement rate for brand drugs when a multiple source brand is preferred on the PDL or if the prescription is written as brand medically necessary.

Application of Drug Category Overrides

Since the primary purpose of the drug category field in the CMS covered outpatient drug product file is to support the Medicaid Drug Rebate Program (MDRP) for the calculation and determination of rebates due from manufacturers to state Medicaid programs, it is necessary to make some adjustments to the application of these values to assist in their use as a basis for payment. Cost data for single source ('S') and innovator multiple source ('I') products are separated from non-innovator multiple source ('N') products for NADAC calculations. The 'S', 'I', and 'N' designations are determined using the most current CMS covered outpatient drug product file. Processes to override the drug category to generally align with reimbursement designations used by states is described in further detail in the "NADAC Reporting Level" section of this document.

The following is an example of the use of the drug category and drug category overrides for NADAC purposes.

Example 2: Use of Drug Category Overrides for Application of NADACs to Individual NDCs

| Drug Name (Labeler) | NDC | Drug Category | NADAC Per Unit | Note |
|-------------------------------------------|---------------|---------------|----------------|---------------------------------------------------------------------|
| Lipitor 10mg tablet (Manufacturer A) | xxxxx-xxxx-xx | S/I | 2.00000 | - |
| atorvastatin 10mg tablet (Manufacturer B) | xxxxx-xxxx-xx | N | 1.00000 | - |
| atorvastatin 10mg tablet (Manufacturer C) | xxxxx-xxxx-xx | N | 1.00000 | - |
| atorvastatin 10mg tablet (Manufacturer D) | xxxxx-xxxx-xx | S/I | 1.00000 | Overridden to a generic drug NADAC due to authorized generic status |

Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for this drug grouping.

This example illustrates the use of drug category overrides for the application of NADACs to NDCs.

In this example, Lipitor 10mg tablet is a brand drug and the NADAC that applies to this NDC within this drug grouping has a drug category of 'S/I'. Atorvastatin made by

manufacturers B and C are generic drugs, and the NADAC that applies to these NDCs within this drug grouping have a drug category of 'N.'

The NDC for atorvastatin made by Manufacturer D has a drug category of 'S/I' on the covered outpatient drug file. However, it is an authorized generic drug so state Medicaid programs may consider this drug to be a generic drug and in such situations, the drug category is overridden.

Application of Differential NADACs Based on Package Size

There are some situations where exceptions to NADAC drug grouping are applied to ensure appropriate drug grouping. While most NADAC drug groupings will consist of all package sizes available, a separate NADAC may be calculated for package sizes within a drug grouping when the drug form is 'ml' or 'gram' and when there is a demonstrated variation in acquisition costs between package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing (e.g., topical creams and ointments). Drug forms with kits will also be evaluated for pricing per package size. These situations require the use of differential NADAC drug groupings that vary by package size. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / package size combinations.

Application of Differential NADACs Based on Drug Class

Another situation of exceptions to the typical NADAC drug grouping process is calculating separate NADACs based upon a drug's class. Drug class is based on whether a prescription is required for dispensing a drug product. If a prescription is required, the NDC is referred to as 'legend.' If a prescription is not required, the NDC is referred to as 'over-the-counter,' or 'OTC.' The OTC field on the NADAC file will indicate whether the NDC is considered legend or OTC.

Different NADAC groups are assigned in cases where NDCs within a NADAC drug grouping share identical active ingredients, strength, dosage form, and route of administration but differ by drug class. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / drug class combinations. In other words, NADACs for legend drugs are calculated only from costs for legend drug NDCs. Also, over-the-counter (OTC) drugs are calculated only from costs for OTC NDCs. As with all Medicaid covered outpatient drugs, a prescription is required.

Application of Differential NADACs Based on Therapeutic Equivalency

Therapeutic equivalency is the equivalency rating assigned by the FDA as reported in the Orange Book. The majority of NADAC drug groupings will consist of NDCs that share the same therapeutic equivalency. For a small number of NADAC drug groupings where NDCs share identical active ingredients, strength, dosage form, and route of administration but differ by therapeutic equivalency, there is a need to subdivide the group and calculate separate NADACs per therapeutic equivalency code. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / therapeutic equivalency combinations. In other words, NADACs for drugs with a specific therapeutic equivalency code are calculated only from costs for NDCs with that specific therapeutic equivalency code.

Application of Differential NADACs Based on Multiple Brand Manufacturers Within the Same NADAC Grouping

Brand drug NADAC will generally be based upon the products from a single manufacturer that is identified as the innovator of the drug grouping. There are situations where products from more than one manufacturer within a drug grouping are classified as brand drugs by state Medicaid programs and separate NADACs are calculated per manufacturer product within the same drug grouping.

Statistical Validity

Validity means that that the sample mean is an accurate estimate of the true mean and the sample mean is estimated precisely. Simple random sampling helps to ensure accuracy as the sample reflects the characteristics of the population. Precision depends upon the characteristics of the sample. In particular, as the observations in the population become more concentrated around a single value, the sample mean becomes more precise.

Brand drug NADACs exhibit a high level of precision, demonstrated by low margins of error. For brand drugs, 99.3% of NADACs have a margin of error of less than 5% of the mean unit cost at a confidence interval of 95%. In other words, 99.3% of the NADACs for brand drugs are within 5% of the true average drug cost 95 out of 100 times. The average margin of error as a percent of the mean unit cost is very low at 0.5%, at a confidence level of 95%. For context, the average per unit NADAC for brand drugs is approximately \$5.00

As with brand drug NADACs, calculations for generic drug NADACs result in high levels of precision with low margins of error. For generic drugs, 100% of NADACs have a

margin of error of less than 10% of the mean unit cost at a confidence interval of 95%. In other words, 100% of the NADACs for generic drugs are within 10% of the true average drug cost 95 out of 100 times. The average margin of error as a percent of the mean unit cost is very low at 2.4%, at a confidence level of 95%. For context, the average per unit NADAC for generic drugs is approximately \$0.28000.

NADAC Updates

NADAC file updates occur on a weekly and monthly schedule.

Non-innovator multiple source drugs (Generic drugs)

After an initial NADAC has been determined using the results of the monthly pharmacy acquisition cost surveys, it is reviewed for updates on both a weekly and monthly schedule.

On a weekly basis, the NADACs for generic drugs are reviewed and adjusted as necessary based on research initiated by pharmacy inquiries into the NADAC Help Desk. If research, such as evaluating marketplace availability and contacting other pharmacies, substantiates that a change in price for a generic drug has occurred, a revised NADAC is calculated and included in the next weekly NADAC reference file update. Refer to the “Help Desk Support Functions” section of this document for further details.

Provider inquiries regarding the NADAC will be investigated and evaluated based upon invoice data collected from the pharmacy initiating the review, additional pharmacies contacted by the help desk, and other market factors, such as compendia price changes. NADACs will be adjusted when drug pricing changes have been substantiated and those adjustments will be reflected in the NADAC rate updates published on a weekly basis.

In addition, new drugs as identified by CMS that meet the NADAC criteria are added.

On a monthly basis, existing NADACs for generic drugs are replaced with updated NADACs using the results of the ongoing monthly pharmacy acquisition cost surveys. New drugs as identified by CMS that meet the NADAC criteria are also added during the monthly update.

Some existing NADACs may not be updated due to limited subsequent survey data. In these cases, the existing NADAC for the generic drug will remain on the NADAC file until the sooner of 1) the first month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data or updated based on Help Desk review after twelve consecutive months, the NADAC is removed from the NADAC reference file. Once a NADAC can be calculated for a previously removed drug grouping, the NADAC will again appear on the reference file.

Single source or Innovator multiple source drugs (Brand drugs)

Published pricing compendia pricing changes associated with brand drugs are considered prior to the publication of updated NADACs that are based on monthly surveys. Drug costs used for determining the brand drugs' NADAC are adjusted to reflect the relative change in published drug prices, as described below. This ensures that brand drug NADACs are reflective of current drug prices at the time of publication. After a NADAC has been determined using the results of the monthly pharmacy acquisition cost surveys, it is further reviewed for updates on a weekly schedule.

On a weekly basis, the NADACs for brand drugs are reviewed and adjusted as necessary based on changes in published prices. Changes in published prices are measured as the relative percentage difference between the new published price and the previous published price. Therefore, if the published price for a drug increases by 5%, then the NADAC for that drug is also increased by 5%. The pricing change is validated with survey data obtained from the next monthly survey. The relationship between changes in published brand drug prices and changes in actual brand drug prices obtained from surveys are tracked and monitored to ensure that a consistent correlation continues to exist.

Additionally, Myers and Stauffer LC operates a Help Desk to respond to inquiries related to drug price changes that are not reflected on the current NADAC reference file. NADACs are reviewed and adjusted based on research initiated in response to pharmacy inquiries made to the NADAC Help Desk. If research, such as evaluating marketplace availability and contacting other pharmacies, substantiates that a change in price for a generic drug has occurred, a revised NADAC is calculated and included in the next weekly NADAC reference file update. Refer to the "Help Desk Support Functions" section of this document for further details.

On a monthly basis, existing NADACs for brand drugs are evaluated and then updated based on new survey data. For consistency and smoothing purposes, the results of each subsequent monthly pharmacy acquisition cost survey for brand products are compared to the existing brand NADAC to evaluate whether a change is warranted. Historic month-over-month published pricing changes were evaluated to determine trends in pricing. A 2% pricing change variance threshold for brand drug NADACs was established after extensive analysis of published pricing changes. Published pricing changes were very rarely less than 2%. Therefore, changes of less than 2% from the previous month's brand NADAC will not warrant a change in the published NADAC. Since manufacturer published price changes are already being accounted for through the regular weekly processes, small pricing variations observed from month-to-month

are likely reflective of fluctuations due to the composition of responding pharmacies and not related to marketplace changes in the price of the drug. Utilizing this threshold in the evaluation of brand drug NADACs will avoid implementing NADAC adjustments that are not based on changes in marketplace prices.

Conversely, if the 2% variance threshold is exceeded, the current brand drug NADAC is replaced with the new brand drug NADAC based on the latest monthly survey findings. If the threshold is not exceeded, the current brand drug NADAC will remain on the NADAC file with the current Effective Date. Refer to the “Effective Date Assignment” section for details on effective dates.

NADACs for generic drugs do not have thresholds established since prices tend to be more volatile. Due to this volatility in pricing, a smoothing process would only serve to dampen the effects of true changes in market prices. Utilizing changes in published pricing for generic drug NADACs is also not practical since the relationship between reported prices and actual prices do not demonstrate a level of consistency for generic drugs as it does for brand drugs. In other words, published pricing changes for generic drugs has not been shown to represent actual pricing changes. Therefore, the calculated monthly NADACs for generic drugs are utilized without any smoothing processes.

Some existing NADACs may not be updated due to limited subsequent monthly survey data. In these cases, the existing NADAC for brand drugs will remain on the NADAC file until the sooner of 1) the first month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data, or updated due to a change in published drug pricing or Help Desk review based on a pharmacy inquiry after twelve consecutive months, the NADAC is removed from the NADAC reference file. Once a NADAC can be calculated for a previously removed drug grouping, the NADAC will again appear on the reference file.

Addition of NADACs for new drugs not listed on current quarterly CMS covered outpatient drug product file

The CMS covered outpatient drug product file available on Medicaid.gov is updated on a quarterly basis. There may be instances when drugs that are new to the pharmacy marketplace are not listed until the next quarterly covered outpatient drug product file is published. The lag between the availability of the new drug product in the marketplace and its inclusion on the covered outpatient drug product file could potentially delay addition of new drugs to the NADAC file. To address these instances, Myers and Stauffer LC receive updates from CMS with regards to new drug products. The drug

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)

category for the new drug is assigned through the drug category review process discussed in the “NADAC Calculation” section. When acquisition cost data is available for these new drugs, a NADAC is calculated and added to the NADAC reference file.

Deliverables

The NADAC reference file is publically available on CMS' Medicaid website, Medicaid.gov. The most current reference file is posted, and contains all NADACs and associated information. We expect that each file will contain NADACs for approximately 20,000 to 25,000 NDCs.

NADAC Reference File Format and Layout

The NADAC reference file is published as an Excel file. The file is sorted by NDC Description in alphabetical order and contains the following fields:

- NDC Description - Identifies the drug name, strength, and dosage form of the drug product.
- NDC – The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
- NADAC Per Unit – The National Average Drug Acquisition Cost per unit.
- Effective Date – The effective date of the NADAC Per Unit cost.
- Pricing Unit – Indicates the pricing unit for the associated NDC ('ML', 'GM' or 'EA').
- Pharmacy Type Indicator – The source of pharmacy survey data used to calculate the NADAC. 'C/I' indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.
- OTC – Indicates whether or not the NDC is for an over-the-counter (OTC) product ('Y' or 'N').
- Explanation Code – Codes that pertain to how the NADAC was calculated. These codes are identified in an accompanying NADAC Data Field Definitions document that is posted on Medicaid.gov. Refer to Appendix 2 for further information.
- Classification for Rate Setting – Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. NDCs that were considered brand and are approved by the FDA under an Abbreviated New

Drug Application (ANDA) are designated with ‘B-ANDA.’ Please see more information on ‘B-ANDA in the “NADAC Reporting Level” section of this document.

- Corresponding Generic Drug NADAC Per Unit *and* Corresponding Generic Drug NADAC Effective Date are presented in further detail later in this section.

Appendix 1 contains an example of the NADAC reference file.

NADAC Reference File Publication

The NADAC reference file is posted weekly on Medicaid.gov. The file contains all of the NDCs that have an assigned NADAC. Each NADAC reference file update contains a full listing of covered outpatient drug products’ NDCs with assigned NADACs; therefore, this is a full reference file replacement each week. The header of the NADAC reference file indicates whether the NADAC updates reflect the results of the monthly acquisition cost survey or account for the weekly NADAC update processes described in the “NADAC Updates” section. The header will display

<Monthly/Weekly> NADAC Reference File as of <date>

Additional details regarding the reason for specific NADAC pricing changes is available in the NADAC Week-to-Week Comparison File, presented in further detail later in this section.

Once a NADAC is calculated for a drug grouping, the NADAC is only applied to covered outpatient drug NDCs within that group. NADACs are applied to the entire grouping regardless of whether or not costs were collected for a specific NDC within the drug group, however they will not be published for NDCs that are not CMS covered outpatient drugs.

NDCs with CMS Termination Dates that are before the posting date are excluded from the reference file. The updated NADAC reference file will replace the existing reference file available through the Medicaid.gov website. Changes to the NADAC reference file are identified through the Explanation Code field.

In addition to the NADAC reference file, an accompanying NADAC Data Field Definitions document is published to assist in the interpretation of the NADAC reference file. Information in this document includes the field names, field descriptions, and explanation codes.

Effective Date Assignment

The Effective Date associated with a NADAC will depend on whether the NADAC was updated.

- For NADACs that do not change from the previous reference file, the NADAC and Effective Date will carry forward to the new reference file.
- For NADACs that are added or changed from the previous reference file, a new Effective Date is assigned to the NADAC. This Effective Date is the date on which the NADAC becomes effective.

NADACs are posted two months after the surveyed pharmacy invoices are collected and utilized to calculate prices, as illustrated below.

| Description | Month 1 | Month 2 |
|----------------------------------------------------------------------|--------------------------|--------------------------|
| Date of Drug Purchases for Acquisition Costs | November 1 – November 30 | December 1 – December 31 |
| Month of Survey Collection, Processing and NADAC Calculations | December | January |
| Month of NADAC Reference File Publication | January | February |

Please refer to the “NADAC Updates” section for more detail regarding how drug acquisition costs are updated prior to NADAC reference file publication.

Brand and Generic Drug NADACs for Multiple Source Brand Drug NDCs

In cases where a multiple source brand drug NDC and its corresponding generic drug counterpart both have assigned NADACs, the NADAC reference file will list the NADAC for the corresponding generic drug on the same record line as the multiple source brand

NDC. The effective date associated with the corresponding generic drug NADACs will also be shown on the same record line.

The NADAC reference file contains two columns where the corresponding generic drug NADAC information is contained. These columns are:

- Corresponding Generic Drug NADAC Per Unit – The NADAC for the corresponding generic drug.
- Corresponding Generic Drug NADAC Effective Date – The effective date of when the corresponding generic drug NADAC is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned.

The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears, b) the current corresponding generic drug NADAC effective date plus one day - one day is added to the previous date so that there are no overlapping rate segments, or c) the NADAC Effective Date for the generic drug group. This date assignment process is necessary to update the corresponding generic drug NADACs.

The corresponding generic drug NADAC columns will not be populated when 1) the NDC is not a multiple source brand drug, or 2) there is no NADAC for the corresponding generic drug.

NADAC Week-to-Week Comparison File

A separate file is published on the CMS Medicaid website, Medicaid.gov, that compares the most current NADAC reference file with the immediately preceding NADAC reference file. This comparison file is updated and published on a weekly basis.

The comparison will only consist of NDCs whose NADACs have changed since the previous NADAC reference file. The file will *not* be inclusive of all NDCs in the NADAC reference file. New NDCs or terminated NDCs are not included in this file. NDCs whose NADACs have not changed since the previous NADAC reference file will not be included in this file.

The file is sorted by NDC Description and will contain the following fields:

- NDC Description – Identifies the drug name, strength and dosage form of the drug product.
- NDC – The National Drug Code (NDC) is the numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
- Old NADAC Per Unit – The National Average Drug Acquisition Cost per unit from the previous NADAC Reference File.
- New NADAC Per Unit – The National Average Drug Acquisition Cost per unit from the current NADAC Reference File.
- Classification for Rate Setting – Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA').
- Percent Change – The difference between the New NADAC Per Unit and the Old NADAC Per Unit, divided by the Old NADAC Per Unit.
- Primary Reason – Describes the primary reason for the NADAC Per Unit change, see explanation below for each reason:
 - Survey Rate: The NADAC Per Unit has been updated using information from the most recently completed pharmacy survey.
 - WAC Adjustment: The NADAC Per Unit has been updated to reflect changes in published pricing.
 - Help Desk Adjustment: The NADAC Per Unit has been updated as a result of an inquiry to the help desk.
 - Brand Generic Change: The NADAC Per Unit has been updated as a result of a change in the Classification for Rate Setting.

- Rate Group Change: The NADAC Per Unit has been updated due to placement into a new NADAC drug grouping because of a change in NDC attributes.

In addition to the NADAC Week-to-Week Comparison File, an accompanying NADAC Week-to-Week Comparison File Field Definitions document is published to assist in the interpretation of the file. Information in this document includes field names, field descriptions, and primary reasons.

Appendix 5 contains an example of the NADAC Week-to-Week Comparison File. Appendix 6 contains the NADAC Week-to-Week Comparison File data field definitions.

Quality Assurance

Myers and Stauffer LC fully incorporates quality assurance procedures to ensure that acquisition cost submissions are reasonable (as discussed below), are associated with valid, active NDCs, and calculations are performed in accordance with the methodology outlined in this document.

Prior to initiation of NADAC calculations, data is reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Quality assurance checks are performed to ensure that acquisition costs are being reported and not being substituted with commercial pricing benchmarks such as AWP. For an entire submission from one pharmacy, the percentage of costs reported that are equal to or greater than AWP is calculated. If costs equal to or above AWP meet an established threshold in the aggregate, further investigation is initiated to ensure that actual cost data is submitted.

As part of this investigation process, individual pharmacies are contacted if there are questions with the pharmacy's acquisition cost submissions. As described earlier in the "NADAC Calculation" section, price outliers are removed through two processes. The first process removes all cost observations that are not within two (2) standard deviations from the mean acquisition cost for the drug grouping. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining a large majority of values used to calculate a mean.

The second process is a manual review of the NADAC calculations. A drug-by-drug review is conducted by a review team comprised of pharmacists and analysts to ensure that reliable NADAC calculations have been performed. These reviews consist of measures to determine the reliability of the NADACs. The array of invoice costs collected are carefully analyzed to determine if factors such as price increases or drug shortages during the invoice collection period may have adversely impacted the NADAC calculation. Obvious outliers, data entry/data import errors and package size discrepancies are identified and addressed. NADAC files are reviewed weekly and monthly to ensure consistency of drug groups, drug categories, and NDC counts. Additionally, large increases and decreases in NADACs prompt further research to confirm drug price changes.

These quality assurance measures prevent outlier acquisition costs from inappropriately impacting the NADAC calculation, distinguish potential inconsistencies in data, proactively identify changes that require further investigation, and ensure reliable NADAC calculations. Myers and Stauffer LC also performs an ongoing quality review of

calculations and procedures for the acquisition cost survey and NADAC reference file publication in order to continue to refine these processes. Examples of quality assurance analyses used for this type of review include monitoring price change trends compared to published price references and comparison of acquisition costs across various pharmacy characteristics, such as chain or independent pharmacies

Help Desk Support Functions

Myers and Stauffer LC supports a NADAC Help Desk, which is staffed with certified pharmacy technicians, trained analysts, and pharmacists. This Help Desk will assist pharmacies and state Medicaid agencies with the following types of issues only.

- Survey Support - Pharmacies are able to contact Myers and Stauffer LC with questions related to the survey, survey process, options for responding to the survey, what information to submit, or other related questions.
- Drug Price Changes – Pharmacies are able to provide notification of recent drug price changes that are not reflected in posted NADACs to the Help Desk. Help Desk staff may request additional information to assist in the research of these changes, such as invoices or screen shots of drug ordering systems reflecting current acquisition costs.

The Help Desk will receive and address each inquiry. Research will be performed to validate claims of drug pricing changes. Such research will include comparison to costs collected through the survey, confirmation of drug or material shortages, and confirmation of drug price changes with other pharmacies. Pharmacies will be informed that changes made to the NADAC as a result of the inquiry will be addressed in future published reference files. Providers can contact the Help Desk to receive an update on the status of their question if they are unclear of whether a NADAC was updated.

The Help Desk will not address pharmacy inquiries into specific State or claim reimbursement related questions or concerns.

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

Toll-free phone: (855) 457-5264
Electronic mail: info@mslcrps.com
Facsimile: (317) 815-5478

Glossary

| <i>Term</i> | <i>Definition</i> |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Active Ingredient(s)</i> | The active ingredient(s) represents the text description of the generic name of the drug product for the NDC. |
| <i>Classification for Rate Setting</i> | Indicates whether the NDC was brand ('B') or generic ('G') for the NADAC rate calculation process. NDCs that were reported brand and are approved by FDA under an Abbreviated New Drug Application (ANDA) are designated by 'B-ANDA.' |
| <i>CMS Termination Date</i> | Date the drug was withdrawn from market or the drug's last lot expiration date. |
| <i>CMS Drug Category</i> | 'S/I' drug or 'N' drug, as determined through the 'Single-source', 'Innovator Multiple Source', and 'Non-innovator Multiple Source' drug category designations listed on the most current CMS outpatient covered drug product file. |
| <i>CMS DESI Code</i> | Drug Product Efficacy Study and Implementation (DESI) codes obtained from the CMS covered outpatient drug product file. Products must not have a code that indicates that it is less than effective. Such drugs, identified by having a CMS DESI code of 5 or 6, are excluded from NADAC calculations. |
| <i>Corresponding Generic Drug NADAC Per Unit</i> | The NADAC for the corresponding generic drug that is assigned to a multiple source brand drug NDC. |
| <i>Corresponding Generic Drug NADAC Effective Date</i> | The date when the corresponding generic drug NADAC is assigned to a multiple source brand drug NDC. |

| Term | Definition |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Drug Grouping | The drug grouping is based on active ingredient, strength, dosage form, and route of administration for a formulation. In some cases, the drug grouping is further differentiated by package size. This additional delineation occurs when there is a demonstrated variation of acquisition cost among package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing. |
| Effective Date | The effective date of the NADAC Per Unit cost. |
| Explanation Code | Codes that pertain to how the NADAC was calculated. These codes are identified in an accompanying NADAC Data Field Definitions document that is posted on Medicaid.gov. Refer to Appendix 2 for further information. |
| NADAC | The National Average Drug Acquisition Cost (NADAC). Represents a national pricing benchmark that is reflective of actual invoice costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from retail community pharmacies and reflects actual drug purchases. |
| NDC | The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code. |
| NDC Description | Identifies the drug name, strength, and dosage form of the drug product. |

| Term | Definition |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Obsolete Date | The estimated date reported by the manufacturer, that indicates the NDC is to be discontinued, no longer marketed, no longer produced, no longer distributed, or otherwise made unavailable to the marketplace. This date is obtained from drug information compendia. |
| Outlier | Drug cost observations that exhibit a deviation from other known cost observations for similar drugs. The two standard deviation approach combined with a manual review is the most effective process for removing outliers. |
| Pharmacy Type | <p>A category of pharmacies. Entities such as chain and independent pharmacies (C/I), as determined through self-reported pharmacy identification, or other supplemental resources. This information is obtained from a national pharmacy compendia file.</p> <p>A chain pharmacy is defined as a pharmacy that belongs to a group of four or more pharmacies that are all under the same ownership and all have the same name. An independent pharmacy is defined as a pharmacy that is not owned or operated by a chain. Franchise pharmacies are classified as independent pharmacies.</p> |
| Pricing Unit | Indicates the pricing unit for the associated NDC (e.g., 'ML', 'GM', or 'EA'). |
| Specialty Pharmacy | Pharmacies that dispense specialty drugs, as identified by the classification of their pharmacies as primarily specialty pharmacies in the National Council for Prescription Drug Programs (NCPDP) database. In addition, URAC specialty pharmacy certification is used as a supplement to identify specialty pharmacies. |

Appendix

- 1) Sample NADAC Reference File
- 2) NADAC Data Fields Definitions
- 3) Survey Letter and Cover Sheet
- 4) Paperwork Reduction Act Statement
- 5) Sample NADAC Week-to-Week Comparison File
- 6) NADAC Week-to-Week Comparison File Data Fields Definitions

APPENDIX 1: Sample NADAC Reference File, with a deliverable date of 2/15/2013

| NDC Description | NDC | NADAC Per Unit | Effective Date | Pricing Unit | Pharmacy Type Indicator | OTC | Explanation Code ¹ | Classification for Rate Setting | Corresponding Generic Drug NADAC Per Unit | Corresponding Generic Drug NADAC Per Unit |
|-----------------|---------------|----------------|----------------|--------------|-------------------------|-----|-------------------------------|---------------------------------|-------------------------------------------|-------------------------------------------|
| Drug A 5mg Tab | xxxxx-xxxx-xx | 0.12345 | 1/1/2013 | Tablet | C/I | N | 1,6 | G | - | - |
| Drug B 5mg Tab | xxxxx-xxxx-xx | 6.54321 | 2/1/2013 | Tablet | C/I | N | 1 | B | 0.12345 | 2/15/2013 |
| Drug C 15mg Tab | xxxxx-xxxx-xx | 12.34567 | 2/1/2013 | Tablet | C/I | N | 1 | B-ANDA | 0.98765 | 2/1/2013 |

¹NADAC Attribute - 1 identifies that the posted NADAC reflects the average cost from submitted invoice costs only. NADAC Attribute - 6 identifies that the drug category on the CMS covered outpatient drug product file was not applied (overridden).

In the example above, Drug B is a multisource brand drug and Drug A is its corresponding generic drug. Please refer to the discussion on *Brand and Generic Drug NADACs for Multiple Source Brand Drug NDCs* within the *Deliverables* section of this document for further explanation of the corresponding generic drug NADAC columns.

Drug C is an example of a drug that is classified as a brand drug for purposes of Medicaid payment and is approved by FDA under an Abbreviated New Drug Application (ANDA).

APPENDIX 2: NADAC Data Field Definitions

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) DATA FIELD DEFINITIONS

National Drug Code (NDC) Description:

Identifies the drug name, strength, and dosage form of the drug product.

NDC:

The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.

NADAC Per Unit:

The National Average Drug Acquisition Cost per unit.

Effective Date:

The effective date of the NADAC Per Unit cost.

Pricing Unit:

Indicates the pricing unit for the associated NDC ('ML', 'GM' or 'EA').

Pharmacy Type Indicator:

The source of pharmacy survey data used to calculate the NADAC. 'C/I' indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.

OTC:

Indicates whether or not the NDC is for an over-the-counter (OTC) product ('Y' or 'N').

Explanation Code:

Codes that pertain to how the NADAC was calculated; see explanation codes below:

- Code 1: The NADAC was calculated using information from the most recently completed pharmacy survey.
- Code 2: The average acquisition cost of the most recent survey was within $\pm 2\%$ of the current NADAC; therefore, the NADAC was carried forward from the previous file.
- Code 3: The NADAC based on survey data has been adjusted to reflect changes in published pricing, or as a result of an inquiry to the help desk.
- Code 4: The NADAC was carried forward from the previous file.
- Code 5: The NADAC was calculated based on package size.

- Code 6: The CMS Covered Outpatient File drug category type of 'S/I/N' (Single Source/Innovator/Non-Innovator) has not been applied. Most 'S/I' drugs with the same strength, dosage form and route of administration were grouped together for the purpose of the NADAC calculation and 'N' drugs were also grouped together. In some cases, however, in calculating a NADAC, the CMS 'S/I/N' designation was not applied when the state Medicaid brand or generic payment practices for these drugs generally differed from the CMS Covered Outpatient File designation.

For example, authorized generic drugs are listed in the CMS covered outpatient drug file as 'I' drugs for the purpose of rebates as they were approved under a New Drug Application (NDA). However, they are grouped as 'N' for the NADAC calculation since they are generally designated as generic by most state Medicaid programs for the purposes of reimbursement. Another example of this occurrence is when proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA) are in the CMS Covered Outpatient Drug file as 'N' for the purpose of rebates. However, they are grouped as 'S/I' for the NADAC calculation since they are generally reimbursed as brand drugs by state Medicaid programs.

- Codes 7 through 10: Reserved for future use.

Classification for Rate Setting:

Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA').

Corresponding Generic Drug NADAC Per Unit:

The NADAC for the corresponding generic drug.

Corresponding Generic Drug Effective Date:

The effective date of when the Corresponding Generic Drug NADAC Per Unit is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned.

The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears, b) the current corresponding generic drug NADAC effective date plus one day – one day is added to the previous date so that there are no overlapping rate segments, or c) the NADAC Effective Date for the generic drug group. This data assignment process is necessary to eliminate the potential for applying corresponding generic drug NADACs to past claims.

APPENDIX 3: Survey Letter



Center for Medicaid and CHIP Services

March 1, 2013

Dear Pharmacy Owner / Manager:

As you are aware, changes in the availability of drug pricing benchmarks necessitate that many State Medicaid programs evaluate alternative pricing methods for use in reimbursing pharmacies for drugs that they dispense. Because of these changes, we have the unique opportunity to work together to recognize the contributions pharmacists make to the health of Medicaid recipients through the realignment of drug ingredient reimbursement for estimating pharmacy's acquisition costs, and the provision of reasonable Medicaid dispensing fees that consider professional services performed by pharmacists.

The Centers for Medicare and Medicaid Services (CMS) is working with State Medicaid programs, with input from national pharmacy associations and many other stakeholders, regarding the design and development of a National Average Drug Acquisition Cost (NADAC) reference file. We expect that the NADAC reference file will represent a new pricing benchmark based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark will be based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey will be conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date.

CMS envisions that the NADAC reference file will provide State Medicaid agencies with an additional pricing reference which they can use to evaluate their current drug reimbursement methodologies. If a Medicaid program chooses to utilize the NADAC reference file for drug ingredient reimbursement, we expect that States will simultaneously evaluate their Medicaid dispensing fee.

One of the primary goals of this program is to create and maintain an up-to-date NADAC reference list for Medicaid covered outpatient drugs reflecting the average price paid for drugs by entities (e.g., independent pharmacies and chain pharmacies in the United States). The drug acquisition cost survey process has been designed to minimize the administrative burdens on pharmacies that participate and to streamline the process of obtaining drug cost data from pharmacies.

CMS has contracted with Myers and Stauffer LC, a national certified public accounting firm that provides professional accounting, consulting, data management and analysis services to government-sponsored healthcare programs. Myers and Stauffer has extensive experience working with State Medicaid pharmacy programs and collecting acquisition costs directly from pharmacies. Under this CMS contract, Myers and Stauffer has developed a methodology for collecting drug acquisition costs and calculating the NADAC reference file prices for covered outpatient drugs.

A meeting with stakeholders was held on August 4, 2011 at the CMS offices in Baltimore, during which the proposed methodology for the NADAC was presented. Since that meeting, further stakeholder input has been received and considered in the final design and development of the drug acquisition cost survey and NADAC reference file initiative. Additional information and routine updates will be available from the <http://www.Medicaid.gov> website.

Over →
OMB Control #0938-1041

Pharmacy Owner/Manager
March 1, 2013
Page 2

Your pharmacy has been randomly selected to participate in this month's survey. We are requesting that you provide a copy of the selected purchase invoices for drugs purchased by your pharmacy. The attached survey instructions prepared by Myers and Stauffer outline the survey process for submitting one (1) month's worth of drug invoices by fax, mail, or electronic submission. Since 2,000 to 2,500 pharmacies nationwide are randomly selected to participate in the survey each month, the probability that your pharmacy will be selected again during the year is 5% or less. Based on the contractor's experience, it is estimated to take less than 30 minutes of non-pharmacist time to assemble and submit the requested information.

It is important to note that all drug purchase price information submitted for this project will remain under the control of CMS, will only be used for the purposes described above, and will remain secure to the extent provided by law, consistent with Exemption 4 of the Freedom of Information Act (FOIA). Accordingly, neither CMS nor Myers and Stauffer will release invoice information and pharmacy identification that is submitted voluntarily and is identified by you as proprietary, except as is required by law.

By participating in the survey, you will have the opportunity to ensure that the market conditions facing your pharmacy are represented in the calculation and evaluation of the NADAC. One of the goals of the NADAC program is to account for the prices that pharmacies pay to acquire drugs.

To accomplish this goal, information from your pharmacy is necessary. Your participation in this endeavor is strongly encouraged and greatly appreciated.

This Retail Price Survey represents an opportunity for Medicaid pharmacies to participate in an initiative to determine a reference price representing the acquisition cost of drugs. Please note that current Federal regulations require State Medicaid programs to consider the professional services performed when setting their dispensing fee rates.

Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions regarding this survey.

Sincerely,

Barbara Coulter Edwards
Director, Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services

OMB Control #0938-1041



Center for Medicaid and CHIP Services

**National Average Drug Acquisition Cost (NADAC)
Survey Request for Information**

March 1, 2013

Your pharmacy has been randomly selected for a sampling of invoices. **We are requesting your pharmacy provide the following information within 14 days:**

- | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1) Copies of all wholesaler, distributor, or manufacturer invoices, reflecting all brand, generic and OTC drug purchases transacted with all your wholesale supplier(s) and/or drug manufacturer(s) between February 1, 2013 through February 28, 20132) Enclosed Cover Sheet (on gold-colored paper), if identifying submitted information as proprietary and confidential |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

These records are to be limited to drug ingredient costs only. All costs that are not drug ingredient costs, such as those for shipping, storage, warehousing, or other administrative costs or other internal mark-ups, will not be considered when calculating the NADAC. For purposes of this survey, drug ingredient costs should represent the invoice price paid by your pharmacy to an unrelated third party supplier of outpatient drugs, such as your wholesaler or drug manufacturer. Drug ingredient costs charged to your pharmacy by related parties that also include administrative costs or other mark-ups will not be included in the NADAC calculations. Please do not submit any patient-identifiable information.

Information should be submitted in printed or electronic format and should include the following information:

- 1) National Drug Code (NDC)
- 2) Purchase price of drug (drug ingredient cost only – see instructions above)
- 3) Quantity purchased
- 4) Purchase date for each product
- 5) “Item number”-to-NDC crosswalk, if item numbers or other proprietary nomenclature is used on your invoices.

As a time-saving alternative to you or your pharmacy staff submitting invoice records, you may contact your drug supplier(s) to request and authorize them to forward an electronic or hard copy of your purchasing history (as described above) for the requested period directly to Myers and Stauffer LC.

Please do not include any invoices that include Public Health Services 340B drug pricing.

Over →
OMB Control #0938-1041

March 1, 2013
Page 2

Information should be mailed, faxed, or sent electronically to the following address within 14 days:

Myers and Stauffer LC

Attention: CMS Pharmacy Survey
9265 Counselors Row, Suite 200
Indianapolis, IN 46240-6419

OR

317-815-5478 FAX

OR

survey@mslcrps.com (Please indicate “**CMS Pharmacy Survey – confidential and proprietary**” in the subject line.)

***** PLEASE USE THE ENCLOSED COVER SHEET (ON GOLD-COLORED PAPER) WHEN SUBMITTING YOUR PHARMACY'S INFORMATION TO IDENTIFY THIS INFORMATION AS PROPRIETARY. FAILURE TO DO SO MAY MEAN IT WILL NOT BE CONSIDERED PROPRIETARY.**

Please be aware that information submitted will not be returned, therefore, please submit copies or electronic files of these records. Your participation in this endeavor is strongly encouraged and greatly appreciated. Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1041**. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

OMB Control #0938-1041



Center for Medicaid and CHIP Services

COVER SHEET

National Average Drug Acquisition Cost (NADAC) Survey Request for Information

TO: Myers and Stauffer LC
ATTENTION: CMS Pharmacy Survey

9265 Counselors Row, Suite 200

Indianapolis, IN 46240-6419

OR

317-815-5478 FAX

OR

survey@mslcrps.com

(Please indicate “CMS Pharmacy Survey – confidential and proprietary” in the subject line.)

The data contained in this submission is proprietary and confidential financial information that has been submitted voluntarily.

OMB Control #0938-1041

APPENDIX 4: Paperwork Reduction Act Statement

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1041**. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

APPENDIX 5: Sample NADAC Week-to-Week Comparison File

| NDC Description | NDC | Old NADAC Per Unit | New NADAC Per Unit | Classification for Rate Setting | Percent Change | Primary Reason |
|------------------------|---------------|---------------------------|---------------------------|----------------------------------------|-----------------------|-----------------------|
| Drug A 5mg Tab | xxxxx-xxxx-xx | 0.12345 | 0.10234 | G | -17.10% | Survey Rate |
| Drug B 5mg Tab | xxxxx-xxxx-xx | 6.54321 | 6.78901 | B | 3.76% | WAC Adjustment |

In the example above, Drug A and Drug B have NADACs in a previous and current NADAC Reference File.

The NADAC for Drug A decreased by 17.10% from the previous NADAC due to results of the monthly pharmacy acquisition cost survey.

The NADAC for Drug B increased by 3.76% from the previous NADAC based upon changes to the Wholesale Acquisition Cost (WAC).

APPENDIX 6: NADAC Week-to-Week Comparison File Data Field Definitions

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) WEEK TO WEEK FILE COMPARISON DATA FIELD DEFINITIONS

National Drug Code (NDC) Description:

Identifies the drug name, strength and dosage form of the drug product.

NDC:

The National Drug Code (NDC) is the numerical code maintained by the FDA that includes the labeler code, product code, and package size code. The NDC is an 11-digit code.

Old NADAC Per Unit:

The National Average Drug Acquisition Cost per pricing unit from the previous NADAC Reference File.

New NADAC Per Unit:

The National Average Drug Acquisition Cost per pricing unit from the current NADAC Reference File.

Classification for Rate Setting:

Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA').

Percent Change:

The difference between the New NADAC Per Unit and the Old NADAC Per Unit, divided by the Old NADAC Per Unit.

Primary Reason:

Describes the primary reason for the NADAC Per Unit change, see explanation below for each reason:

- **Survey Rate:** The NADAC Per Unit has been updated using information from the most recently completed pharmacy survey.
- **WAC Adjustment:** The NADAC Per Unit has been updated to reflect changes in published pricing.
- **Help Desk Adjustment:** The NADAC Per Unit has been updated as a result of an inquiry to the help desk.

**NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC)
WEEK TO WEEK FILE COMPARISON
DATA FIELD DEFINITIONS**

- Brand Generic Change: The NADAC Per Unit has been updated as a result of a change in the Classification for Rate Setting.
- Rate Group Change: The NADAC Per Unit has been updated due to placement into a new NADAC drug grouping because of a change in the NDC attributes. NDC attributes that may result in a rate group change include package size updates, brand/generic designation redeterminations and revisions to the active ingredient(s), strength, dosage form or route of administration.