DRAFT

The Centers for Medicare & Medicaid Services

Part II:

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

May 2012

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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 retail community pharmacies of retail prices for covered outpatient drugs.

The first part of the survey (Part I) focuses on the retail community pharmacy consumer prices. The Part I methodology will be disseminated for review and comment in another document.

This part of the survey, which is the second part (Part II), will focus on the retail community pharmacy ingredient costs. This will provide for a survey of the acquisition costs of covered outpatient drugs purchased by retail community pharmacies, which will include purchase prices derived from independent community pharmacies and chain pharmacies.

Section 1927(f) also provides for the calculation of the monthly national retail community pharmacy prices of covered outpatient drugs. It includes reporting by the States of payment and certain utilization rates for the 50 most widely prescribed drugs, and comparing State drug payment rates with the national retail survey prices.

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 dispensing costs. In general, Federal regulations require that Medicaid 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, the estimated acquisition cost (EAC) is the State's best estimate of the acquisition cost generally and currently paid by Medicaid-participating pharmacies for a drug marketed or sold by manufacturers or labelers in the package size of the drug most frequently purchased by providers. Most Medicaid agencies currently utilize published drug pricing benchmarks to determine the EAC for drug ingredient costs.

The Average Wholesale Price (AWP) is a key drug pricing benchmark that, until recently, was commonly utilized as one of the standards in pharmaceutical reimbursement by State Medicaid agencies. However, this benchmark has been the subject of scrutiny and litigation stating that many AWPs were artificially inflated. The effect of this inflation could result in an overstatement of estimated acquisition costs and consequently the overpayment 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]

In part as a result of litigation concerning AWP, drug pricing compendia have reversed the inflated prices listed in the published AWP, effective September 2009. In addition to this change, a pharmacy data publisher of AWP chose to discontinue publication of AWP in September 2011, further creating a need for alternative methods for states to determine drug ingredient costs. Utilization of other published drug pricing benchmarks is an option that States commonly consider. Such alternatives include Wholesale Acquisition Cost (WAC), Average Sales Price (ASP), and Direct Price (DP).

In late 2009, a working group within the National Association of State Medicaid Directors (NASMD) convened to discuss the various considerations related to this topic. The working group authored a white paper in June 2010 entitled "Post AWP Pricing and Reimbursement" that evaluated the issues and developed options for the replacement of AWP in reimbursement methodologies. Among the recommendations presented in the white paper was the establishment of a single national price benchmark for pharmacy reimbursement based on average drug acquisition costs. Such a benchmark would provide State Medicaid agencies with a better estimate of prices paid by pharmacies for drugs because it would be based upon actual drug purchase experience. This approach to drug ingredient price determination provides greater accuracy and transparency in how drug prices are established. The NASMD requested that CMS coordinate, develop, and support this benchmark. 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 retail community pharmacies of retail prices for covered outpatient drugs. The statute provides that such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The statute further contemplates that the contractor provide notification when a drug product becomes generally available and that the contract include such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. CMS expects that ingredient cost data would provide information to assist CMS in carrying out its responsibilities and to the States in setting drug payment rates through the state plan amendment process. The National Average Drug Acquisition Cost (NADAC) file will allow for covered outpatient drug products to be reimbursed more effectively.

Purpose

[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

The purpose of the NADAC is to create a new national price benchmark that is more reflective of the prices that pharmacies pay to acquire prescription and over-the-counter drugs. The statute provides that such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The survey data will provide information which CMS expects to use to assure compliance with Federal requirements.

A monthly nationwide survey of licensed retail community pharmacies, which will include independent pharmacies and chain pharmacies in the United States, will be performed to collect drug acquisition cost information. To ensure that NADACs are accurate, timely, and robust, the NADACs will be reviewed and updated on a weekly basis. The NADAC will be available for consideration by the States to assist with their individual pharmacy reimbursement policies.

CMS has contracted with Myers and Stauffer LC, a national certified public accounting firm, to conduct the surveys of drug ingredient costs from pharmacy entities, such as independent pharmacies and chain pharmacies in the United States, and to develop and maintain the NADAC pricing benchmark.

Level of Reporting

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

Drug grouping will allow the same NADAC to be applied to the NDCs of identical products. It is based on the active ingredient(s), strength, dosage form, and route of administration. NDCs for drugs that are therapeutically and pharmaceutically equivalent will belong to the same drug grouping. In some cases, additional parameters are included in the definition of a drug grouping. For example, package size will be included for additional delineation when there is a demonstrated variance of acquisition costs among 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 category is obtained from the most recent quarterly CMS covered outpatient drug product file. It classifies each NDC listed in the file as one of the following: Single source (S), Innovator multiple source (I), or Non-innovator multiple source (N). NDCs designated as S and I will be considered S or I drugs and NDCs designated as N will be considered N drugs for purposes of the NADAC calculation. S or I drugs will have separate NADACs than N drugs. A drug grouping may have an S/I drug and an N drug

NADAC if NDCs with those drug categories are included in the drug grouping. An NDC will only have an S/I drug, or an N drug NADAC; it will not be assigned both.

The S/I/N designation in the covered outpatient drug product file is related to a drug's rebate status but may not always correspond with the manner in which States classify a drug for reimbursement purposes. In cases where the S/I/N designation for an NDC does not correspond with the designation that the States use for drug reimbursement, an override process will be implemented to ensure that the calculation of the NADAC reflects reimbursement policy. The override process will consist of the following steps:

- The S/I/N designation of each NDC in the Covered Outpatient Drug product file will be compared to the brand/generic designation of State reimbursement methodology to identify cases in which they commonly conflict.
- CMS will review and approve the proposed S/I/N overrides for NADAC calculation purposes.

The goal of the override process is to address cases where the S/I/N designation would not accurately reflect the reimbursement policy utilized by the States, for example when an "S" drug has therapeutic equivalents.

Pharmacy entity type is the identification of a pharmacy as chain or independent. The pharmacy type is obtained from a national self-reported pharmacy identification database. However, other supplemental resources may be used to verify the pharmacy type. There will be separate NADACs based on drug costs collected from different types of pharmacy entities, such as independent pharmacies and chain pharmacies in the United States. The NADACs for each pharmacy entity type will be based upon the acquisition costs obtained through survey from the corresponding pharmacy entity types. These price lists are not mutually exclusive so a drug grouping may appear with NADACs from different pharmacy entity types, though these NADACs would be based on acquisition costs from each respective pharmacy entity type. A Pharmacy Entity Type field in the reference file will distinguish between different types of pharmacy entities.

The designation of these three indicators will determine which NADAC will be applicable to a given situation. The following example illustrates this concept.

Example 1:

Drug NADACs

Drug Grouping	Drug Category	Pharmacy Entity Type	NADAC

Lipitor (atorvastatin) 10mg tablets	S/I	C/I	2.00000
	N	C/I	1.00000

Drug NADACs applied to individual NDCs

Drug Grouping	NDC	Drug Category[1]	Pharmacy EntityType[2]	NADAC
Lipitor 10mg tablet	xxxxx-xxxx-xx	I	C/I	2.00000
	xxxxx-xxxx-xx	I	C/I	2.00000
atorvastatin 10mg tablet	xxxxx-xxxx-xx	N	C/I	1.00000

[1] Drug Category values in this example are reported on CMS Quarterly Covered Outpatient Drug product file.
[2]Pharmacy Entity Type C/I = Chain and independent pharmacies.
Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for these drug groupings.

This example illustrates the assignment of NADACs based on drug grouping, drug category and pharmacy type. All NDCs for Lipitor (atorvastatin) 10mg tablets would be classified into one drug grouping since they contain the same combination of active ingredient, strength, dosage form, and route of administration. However, NDCs for Lipitor (atorvastatin) 20mg tablets would be classified into a separate drug grouping, due to the different strengths (10mg versus 20mg).

In the Lipitor (atorvastatin) example, these NDCs reflect drug products that are available only from chain and independent pharmacies; therefore the pharmacy type for the three NDCs is the same. However, since the drug category differs, the NADAC assigned to the NDCs for Lipitor differs from the NDC for atorvastatin.

Data Sources

Myers and Stauffer LC will work with numerous data sources in order to facilitate the collection, calculation, analysis and reporting of the NADAC.

- Pharmacy drug acquisition data will be collected through monthly surveys of pharmacy entities (e.g., independent pharmacies and chain pharmacies in the United States)).
- Drug identification and published pricing information will be obtained from multiple national drug pricing compendia in order to verify that NDCs meet certain NADAC criteria, such as whether their status is valid and active, and if their Medicaid drug rebate DESI code is 5 or 6, for purpose of excluding these from NADAC calculations (refer to the NADAC Calculation section in this document for details).
- A national pharmacy compendia file will be used to identify individual pharmacy characteristics for the survey sample selection and data analysis processes.
- The covered outpatient drug product file will be obtained from Medicaid.gov to use in the NADAC criteria evaluation.

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. There will be a survey of pharmacy entities (e.g., independent pharmacies and chain pharmacies in the United States). National pharmacy compendia files containing information on the retail pharmacies throughout the country will be used to determine the pool of providers eligible for each survey.

Chain and Independent Pharmacy - A random sample of approximately 2,000-2,500 chain and independent pharmacies will be generated on a monthly basis. The sample is drawn from the overall population of such pharmacies. Each month, all such pharmacies are eligible to be selected for the monthly sample. Given the large number of chain and independent pharmacies nationwide (over 60,000), there is less than a 5 percent chance that a pharmacy will be selected twice in a year for a survey. The appendix contains a comparison of the distribution of pharmacy entity characteristics between a survey sample and the pharmacy population. It shows that the composition of the survey sample closely aligns with the composition of the pharmacy population with regards to pharmacy characteristics.

Specialty Pharmacy - Specialty pharmacies will be excluded from the survey at this time. These specialty pharmacies are identified by their classification as primarily specialty pharmacies on the National Council for Prescription Drug Programs (NCPDP) database. Furthermore, the URAC specialty pharmacy certification list is used to identify additional specialty pharmacies for exclusion from the initial survey

Survey Process – Prior to the first of each month, survey letters will be mailed to the physical location address of each selected pharmacy. The survey will request the voluntary submission of drug acquisition cost data from the previous month. Pharmacies will be asked to submit the requested information within 2 weeks. Upon request, survey letters can also be emailed to a pharmacy or, in the case of chain providers, a corporate contact. Reminders will be sent via electronic mail to pharmacies within 10 to 14 days.

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

- NDC
- Unit Price Paid

- Invoice Date
- Quantity Purchased

These items listed will be the only information obtained from submitted documents that will be retained for use in calculating the NADAC. Other information from the submissions will not be used.

We understand this information is found on documentation that is already maintained in the pharmacy and is readily available. Data will be accepted in hard copy and electronic formats. The time needed to respond to the survey request should take no more than 30 minutes of non-pharmacist staff time. Many pharmacy inventory systems have functionality that allows pharmacies to produce and send a report that includes the requested information. In addition, another option for pharmacies to respond to the surveys is to contact their wholesalers to produce and send the requested information on their behalf. Pharmacy invoices that reflect drugs purchased through the 340B program will be excluded. For purposes of this survey, discounts or rebates that are not listed on the invoice will not be collected. In addition to information on drug purchases, pharmacies will be requested to send the cover sheet that accompanies the survey letter. This cover sheet indicates the pharmacy's intent for its submitted information to remain confidential. If the cover sheet is not included in the pharmacy's submission, Myers and Stauffer LC will attempt to contact the pharmacy to confirm the intent to exclude the cover letter. Refer to the appendix of this document for a sample of the survey letter and cover sheet.

Processing of Survey Data

Data submitted for the survey will be 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 responses are received, several tasks are performed to process the submissions. Pharmacy submissions are tracked in a receipt log to ensure that survey responses are 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 attempt to contact the pharmacy to clarify whether this omission was intentional. If the pharmacy chooses to indicate that its submission is confidential, the pharmacy will be asked to also submit the cover letter that accompanies the survey letter to request confidentiality.

Data will be 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 will not be entered into the database. Refer to the background section of this document for further discussion on the AWP and drug prices. If required information (e.g. NDC information) is not submitted or does not appear to be reasonable (e.g. unit cost is equal to or greater than AWP), the submission will be excluded from consideration in the calculation of the NADAC.

After preliminary reviews of the cost data, the data will be loaded into a database in order to be eligible for use in the NADAC calculation.

Data received in electronic format are directly entered into the database. Submissions received in hard copy are manually entered into the database. After data entry is complete, quality assurance procedures will be applied 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 numbers of data lines submitted electronically versus those entered into the database for individual pharmacies.

All submitted survey responses will be stored in a secure and confidential manner. Hard copy files are stored in a locked environment and eventually returned to CMS or destroyed upon CMS direction in accordance with the 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

These processes apply to NADAC calculations for various entities (e.g., independent pharmacies and chain pharmacies in the United States).

Prior to any calculations, the data are classified according to:

- Drug Category: Single source (S), Innovator multiple source (I), or Non-innovator multiple source (N)
- Pharmacy Entity Type: chain and independent pharmacy (C/I)

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

- Data must be from surveyed pharmacies.
- Cost data must be for valid, active NDCs listed in published pricing compendia. Obsolete NDCs are excluded from NADAC calculations.
- Invoice date must be for the calendar month under review.
- Products must be on the latest CMS covered outpatient drug product file or new drugs determined as covered outpatient drugs as defined by section 1927 of the Social Security Act.
- Products must not have a code that indicates that it has been declared less than effective by the Drug Product Efficacy Study and Implementation (DESI) program. Such drugs, identified by having a DESI code of either 5 or 6, will be excluded. DESI codes will be obtained from the CMS covered outpatient drug product file.
- A product must include only one cost observation per NDC per pharmacy. If a pharmacy submits more than one cost observation for the same NDC, the cost with the latest date of purchase will be used. If a pharmacy submits more than one cost observation for the same NDC with the same purchase date, the lowest cost will be used.

A minimum number of reported drug costs for each drug grouping/drug category/ pharmacy type will be required to calculate a NADAC. This minimum number will be

determined in accordance with the initial pharmacy drug acquisition cost surveys received.

The NADAC for each classification defined by drug grouping, drug category, and pharmacy type will be calculated as the average of the per-pricing unit costs, in accordance with (National Council for Prescription Drug Programs) NCPDP standards, weighted by the submitted acquisition costs. Cost observations greater than +/- two standard deviations from the mean are removed as outliers. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining at least 95% of the values to calculate a revised mean. The dispersion of the prices is measured by the standard deviation. A drug-by-drug review for reasonableness will be also conducted. Once the outliers are removed, the average of the per-pricing unit costs will be re-calculated.

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), it is necessary to make some adjustments to the application of these values to ensure their usefulness for NADAC calculation purposes. Cost data for single source ('S') and innovator multiple source ('I') products will be separated from non-innovator multiple source ('N') products for NADAC calculation. The 'S', 'I', and 'N' designations will be determined using the most current CMS covered outpatient drug product file. Processes to override the drug category to reflect categorization used by States is described in further detail in the Level of Reporting section of this document.

The NADAC for S and I products will be referred to as the S/I drug NADAC. The NADAC for N products will be referred to as the N drug NADAC. Generally, one S/I drug NADAC will apply to all S and I NDCs within a drug grouping. Likewise, one N drug NADAC will apply to all N NDCs within a drug grouping. The following is an example of the use of the drug category and drug category overrides for NADAC purposes.

Example 2:

Drug NADACs

Drug Grouping			
Lipitor (atorvastatin) 10mg tablets	S/I	C/I	2.00000
	N	C/I	1.00000

Drug NADACs applied to individual NDCs

NDC	Drug Name (Labeler)	Drug Category[1]	NADAC	Note
xxxxx-xxxx-xx	Lipitor 10mg tablet (Pfizer)	I	2.00000	-
xxxxx-xxxx-xx	Lipitor 10mg tablet (Pfizer)	I	2.00000	-
xxxxx-xxxx-xx	atorvastatin 10mg tablet (Ranbaxy)	N	1.00000	-
68084-0564-01	atorvastatin 10mg tablet (Amer. Health Packing)	N	1.00000	-
xxxxx-xxxx-xx	atorvastatin 10mg tablet (Watson)	I	1.00000	Overridden to N drug NADAC due to authorized generic status

[1]Drug Category values in this example rare reported on CMS Quarterly Covered Outpatient Drug product file.
Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for this drug grouping.

There will be some situations where exceptions to NADAC calculations will necessarily need to be applied to ensure appropriate drug grouping such as cases where per unit drug prices differ based on package sizes. While most NADAC drug groupings will consist of all package sizes available, certain drug groupings such as some topical products have differential pricing based upon package size. Therefore, these situations will require the use of differential NADAC that varies by package sizes. These NADACs will be calculated for unique drug grouping/drug category/pharmacy type/package size combinations. There may also be other situations where the NADACs will be established based on a product-specific grouping such as cases where multiple innovator products share the same active ingredient(s), strength, dosage form, and route of administration but greatly differ in their per unit pricing.

Prior to the publication of updated reference files, drug costs used for determining the NADAC will be adjusted to reflect the relative changes in published drug prices, as described in the NADAC Updates section of this document. This will ensure NADACs are reflective of current drug prices at the time of publication. Myers and Stauffer LC will maintain a Help Desk to address drug price changes that are not reflected in the NADAC updates. Refer to the section on Help Desk Support Functions within this document for further details.

NADAC Updates

NADAC will be updated to revise existing NADACs or to add new NADACs to the reference file. These NADAC updates will occur on both a weekly and monthly schedule.

Non-innovator multiple source drugs (N drugs)

After the initial NADACs have been determined using the results of the first monthly pharmacy acquisition cost survey, the NADACs will be reviewed for updates on both a weekly and monthly schedule.

On a weekly basis, the NADACs will be reviewed and adjusted as necessary based on research initiated by pharmacy inquiries into the NADAC Help Desk. If research substantiates that a change in price for a drug has occurred, a revised NADAC will be calculated and included in the next weekly reference file update.

On a monthly basis, existing NADACs will be replaced with updated NADACs using the results of the ongoing monthly pharmacy acquisition cost surveys. New drugs will be added that meet the NADAC criteria. If an average drug cost for an existing NADAC cannot be calculated with data from a subsequent monthly pharmacy acquisition cost survey, the existing NADAC for that drug will remain on the reference file until the sooner of 1) a month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data after twelve consecutive months, the NADAC will be removed from the reference file. Once a NADAC can be calculated for the previously removed drug grouping, the NADAC will be appear on the file with the updated NADAC.

Single source or Innovator multiple source drugs (S or I drugs)

After the initial NADACs have been determined using the results of the first monthly pharmacy acquisition cost survey, the NADACs will be reviewed for updates on both a weekly and monthly schedule.

On a weekly basis, the NADACs for S/I drugs will be 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 will also be increased by 5%. The relationship between published and actual drug prices will be tracked to ensure that a direct correlation continues to exist.

In addition to these update processes, NADACs can be reviewed and adjusted based on research initiated by pharmacy inquiries into the NADAC Help Desk. If research substantiates that a change in price for a drug has occurred, a revised NADAC will be calculated and included in the next weekly reference file update. Refer to the Help Desk Support Functions section of this document for further details.

On a monthly basis, existing NADACs will be evaluated and updated as necessary with new survey data. For consistency and smoothing purposes, the results of each subsequent monthly pharmacy acquisition cost survey will be compared to the existing NADAC to evaluate if a change is warranted. Thresholds will be determined through analysis of the initial acquisition cost survey to determine whether an updated NADAC is necessary. For example, analysis of cost differences between various pharmacy entity types compared to differences in published drug prices may determine that changes of less than 2% from the previous month's NADAC would not warrant a change in the published NADAC. Since manufacturer published price changes are already being accounted for through the weekly processes, small pricing variations observed from month-to-month are likely reflective of price fluctuations due to the sample composition and not related to marketplace changes in the price of the drug. Utilizing these thresholds in the evaluation of S/I drug NADACs will avoid NADAC adjustments not based on changes in marketplace prices.

If thresholds are exceeded, the current NADAC will be replaced by the NADAC based on monthly drug prices collected. If thresholds are not exceeded, the current S/I drug NADAC will remain on the reference file with an updated NADAC Date. If an average drug cost for an existing NADAC cannot be calculated with data from a subsequent monthly pharmacy acquisition cost survey, the existing NADAC for that drug will remain on the reference 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 after twelve consecutive months, the NADAC will be removed from the reference file. Once a NADAC can be calculated for the previously removed drug grouping, the NADAC will be appear on the file with the updated NADAC.

NADACs for N drugs will not have thresholds established for smoothing purposes. S and I drugs are typically available from one manufacturer so pricing fluctuations will reflect the price changes of a single supplier. Therefore, if the manufacturer has not changed the price of the drug, price fluctuations are due to another factor, such as sample composition. However, N drugs are available from multiple manufacturers. Price volatility for these drugs is a function of the variety of prices charged by numerous suppliers of these products. Due to the volatility of prices and the subsequent range of

acquisition costs within N drug groups, smoothing to address changes in the sample composition is not necessary.

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

The CMS covered outpatient drug product file available on Medicaid.gov is updated on a quarterly basis. There may be drugs that are new to the pharmacy marketplace that would not be 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 drug to the NADAC file. To address these instances, when the criteria for establishing a NADAC is achieved for these new drugs, they will be reviewed individually to determine if they meet the criteria of covered outpatient drugs. To support this effort, Myers and Stauffer LC will receive interim updates from CMS with regards to new drug products. In addition, a list of drug manufacturers participating in MDRP will be maintained and updated based upon releases from CMS to ensure the most recent drug manufacturer rebate information is used. It is important to note that the assignment of a NADAC to a particular NDC does not constitute the status of the NDC as a covered outpatient drug.

Quality Assurance

Myers and Stauffer LC will fully incorporate quality assurance procedures to ensure that the acquisition cost submissions are reasonable and are associated with valid, active NDCs. Myers and Stauffer LC may contact individual pharmacies if there are questions with the pharmacy's acquisition cost submissions.

Prior to initiation of NADAC calculations, data will be reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Drug costs that are found to be equal to or greater than AWP will not be entered into the database. Refer to the background section of this document for further discussion on the AWP and drug prices.

As described earlier in the NADAC calculation section, the price outliers will be removed through two processes. The first process will be to remove all cost observations that are not within two standard deviations from the mean acquisition cost for each drug grouping. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining at least 95% of the values to calculate a revised mean.

The second process will be to review the NADAC calculations to ensure reasonableness, such as evaluating the range of cost observations used to calculate the NADAC. Costs that do not fall within a reasonable range will be removed. This quality assurance measure prevents outlier acquisition costs from impacting the NADAC calculation.

Myers and Stauffer LC will also perform ongoing quality review of calculations and procedures for the acquisition cost survey and NADAC publication to continue to refine these processes. Quality Assurance analyses that can be used for this endeavor may include monitoring price change trends compared to published price references and comparison of acquisition costs across various pharmacy characteristics.

Help Desk Support Functions

Myers and Stauffer LC will support a NADAC Help Desk, which will be 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 will be 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 - Notification of recent drug price changes not reflected in posted NADACs can be sent to the Help Desk. Help Desk staff may request additional information to assist in the research of these calls.

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 confirm drug price changes with other pharmacies.

Pharmacies will be informed that changes made to the NADAC as a result of the inquiry will be reflected in future published rate files. Understanding that many inquiries will be related to identical topics, the results from research performed on individual inquiries will not be communicated back to the inquiring pharmacy. Changes in NADACs resulting from inquiries will be addressed in future reference files. Providers can contact the Help Desk to receive an update on the status of their question if they are unclear of the resolution.

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: survey@mslcrps.com
Facsimile: (317) 816-4134

Deliverables

We expect to make the NADACS available to the States. There will be one reference file provided that contains the NADAC and associated information. Separate NADACs will be presented for various pharmacy entity types and identified by the Pharmacy Entity Type field.

Reference File Format and Layout

The reference file will be published as a fixed length text file and an Excel file. The file will be sorted by NDC in ascending order and will contain the following fields:

- NDC – 11-digit National Drug Code; limited to NDCs listed on CMS covered outpatient drug product file, or NDCs approved by CMS to be included as covered outpatient drugs.
- Drug Name – Label name associated with the NDC.
- NADAC – National Average Drug Acquisition Cost.
- Pharmacy Entity Type – Identifies whether the NADAC reflects acquisition costs from chain or independent pharmacies (C/I). There may be up to two NADACs for each NDC - one for each pharmacy entity type.
- NADAC Date – Date that the NADAC is transmitted to CMS. Refer to NADAC Date Assignment below.
- NDC Attribute – Codes that pertain to additional attributes about specific NADACs. These codes will be identified in an accompanying narrative that will be posted on Medcaid.gov.

Table 1 is an example of the NADAC file.

Table 1: Sample NADAC Reference File

NDC	Drug Name	NADAC	Pharmacy Entity Type	NADAC Date	NADAC Attribute[1]
xxxxx-xxxx-xx	Drug A	0.05698	C/I	7/1/2012	1,4

[1]NADAC Attribute = 1 identifies that posted NADAC reflects the average cost from submitted invoice costs only. NADAC Attribute = 4 identifies that the drug category on the CMS covered outpatient drug product file has been overridden.

Reference File Publication

The NADAC reference file will be posted on Medicaid.gov weekly. The file will contain all of the NDCs that have an assigned NADAC. Each NADAC file update will contain a full listing of covered outpatient drug products NDCs with assigned NADACs; therefore there will be a full file replacement on a weekly basis. NDCs with CMS Termination Dates that have passed will be excluded from the file. The updated file will replace the existing file on Medicaid.gov. Changes to the NADAC file will be identified through the NDC Attribute code.

In addition to the NADAC file, an accompanying narrative document will be published to assist in the interpretation of the NADAC file. Information in this document will include the field lengths, field descriptions, and NDC Attribute codes.

NADAC Date Assignment

The NADAC Date published on each reference file will be assigned in the following manner:

- Monthly NADAC updates – For monthly NADAC files, the NADAC Date will be assigned the date that the NADAC file is sent to CMS. In cases where the weekly S/I drug NADAC update reflects a published drug price change within the week prior to the file processing, the date of the published drug price change will be the NADAC Date. For NADACs that do not change from the previous reference file, the NADAC will carry forward and will be assigned an updated NADAC Date.
- Weekly NADAC updates – For weekly NADAC files, NADACs that are not adjusted will be carried forward and will retain the NADAC Date from the current monthly file. For NADACs that are adjusted based on relative changes in published drug prices, the date of the published drug price change will be assigned as the NADAC Date.

For NADACs that are adjusted based on inquires through the Help Desk, the NADAC Date will be assigned the date that the weekly NADAC file is sent to CMS.

Glossary

Active Ingredient(s)	The active ingredient(s) represents the text description of the generic name of drug product for the NDC.
CMS Termination Date	Date drug was withdrawn from market or the drug's last lot expiration date.
CMS Drug Category	S or 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.
CMS DESI Code	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 has been declared less than effective by the DESI program. Such drugs, identified by having a DESI code of either 5 or 6, will be excluded from NADAC calculations.
Drug Grouping	The drug grouping will be based on active ingredient, strength, dosage form, and route of administration for a formulation. In some cases, the drug grouping will be further differentiated by package size. This additional delineation will occur when there is a demonstrated variance of acquisition cost among package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing.
Drug Name	The drug name is the labeled product name including active ingredient(s), strength, unit of measure, and dosage form.
Entities	Licensed pharmacies in the United States. Examples of entities include independent pharmacies and chain pharmacies.

NADAC	The National Average Drug Acquisition Cost (NADAC) is the national price benchmark that is reflective of the costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from pharmacies that reflect actual drug purchases.
NDC	The National Drug Code (NDC) is the national classification system for identification of drugs. The NDC is a unique 11- digit code assigned by the drug manufacturer to a specific drug. It identifies the Labeler Code, Product Code, and Package Size Code.
Obsolete Date	The estimated date on which an NDC is reported by the manufacturer, 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 large deviation from other cost observations for similar drugs.
Package size	The package size is the labeled quantity that corresponds to the NDC.
Pharmacy Entity Type	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.
Pricing Unit	The pricing unit is the type of billing unit to be used for a product (each, gram, milliliter).
Specialty Pharmacy	Pharmacies that dispense specialty drugs, as identified by the classification of their pharmacies as primarily specialty pharmacies on the National Council for Prescription Drug Programs (NCPDP) database. In addition, URAC specialty pharmacy certification will be used to identify specialty pharmacies for exclusion from the initial survey.

Appendix

1) Survey Letter
2) Paperwork Reduction Act Statement
3) Comparison of Distributions within a Survey Sample and the Pharmacy Population

APPENDIX 1: Survey Letter

Center for Medicaid and CHIP Services

June 1, 2012

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

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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.

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

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Center for Medicaid and CHIP Services

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

June 1, 2012

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

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**

May 1, 2012 through May 31, 2012

2) **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.

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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

317-816-4134 FAX

OR

survey@mslcrps.com (Please indicate **"CMS Pharmacy Survey"** 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.

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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

317-816-4134 FAX

OR

survey@mslcrps.com
(Please indicate "CMS Pharmacy Survey" 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 2: 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 3: Comparison of Distributions within a Survey Sample and the Pharmacy Population

Retail Price Survey - Part II TEST

Pharmacy Sample Selection Statistics for June 2012 Survey (collection of May Invoices)

Dispenser Class	Rural Indicator	Pharmacies in Universe	Percent of Total Universe	Pharmacies Selected for Sample	Percent of Sample
Chain Pharmacy	R	7,410	12%	330	13%
Chain Pharmacy	U	32,526	53%	1,317	53%
Total Chain Pharmacies		39,936		1,647	
Franchise Pharmacy	R	283	0.5%	10	0.4%
Franchise Pharmacy	U	488	1%	22	1%
Total Franchise Pharmacies		771		32	
Independent Pharmacy	R	6,595	11%	257	10%
Independent Pharmacy	U	14,327	23%	564	23%
Total Independent Pharmacies		20,922		821	
Total Pharmacies		61,629	100%	2,500	100%

State	Number of Pharmacies in State	Percent of Total Universe	Number of Pharmacies in Sample	Percent of Sample	Difference
Alabama	1,268	2.06%	40	1.60%	-0.46%
Alaska	91	0.15%	2	0.08%	-0.07%
Arizona	1,011	1.64%	38	1.52%	-0.12%
Arkansas	720	1.17%	23	0.92%	-0.25%
California	5,767	9.36%	249	9.96%	0.60%
Colorado	772	1.25%	28	1.12%	-0.13%
Connecticut	644	1.04%	33	1.32%	0.28%
Delaware	182	0.30%	10	0.40%	0.10%
District of Columbia	123	0.20%	3	0.12%	-0.08%
Florida	4,653	7.55%	206	8.24%	0.69%
Georgia	2,152	3.49%	96	3.84%	0.35%
Hawaii	193	0.31%	3	0.12%	-0.19%
Idaho	278	0.45%	11	0.44%	-0.01%
Illinois	2,247	3.65%	88	3.52%	-0.13%
Indiana	1,115	1.81%	47	1.88%	0.07%
Iowa	693	1.12%	41	1.64%	0.52%
Kansas	597	0.97%	16	0.64%	-0.33%
Kentucky	1,076	1.75%	52	2.08%	0.33%
Louisiana	1,100	1.78%	46	1.84%	0.06%
Maine	285	0.46%	10	0.40%	-0.06%
Maryland	1,115	1.81%	43	1.72%	-0.09%
Massachusetts	1,112	1.80%	46	1.84%	0.04%

Prepared by Myers and Stauffer LC Page 1 May 22, 2012

State	Number of Pharmacies in State	Percent of Total Universe	Number of Pharmacies in Sample	Percent of Sample	Difference
Michigan	2,339	3.80%	99	3.96%	0.16%
Minnesota	979	1.59%	35	1.40%	-0.19%
Mississippi	761	1.23%	25	1.00%	-0.23%
Missouri	1,193	1.94%	46	1.84%	-0.10%
Montana	223	0.36%	14	0.56%	0.20%
Nebraska	419	0.68%	14	0.56%	-0.12%
Nevada	435	0.71%	20	0.80%	0.09%
New Hampshire	256	0.42%	7	0.28%	-0.14%
New Jersey	1,944	3.15%	71	2.84%	-0.31%
New Mexico	287	0.47%	12	0.48%	0.01%
New York	4,703	7.63%	200	8.00%	0.37%
North Carolina	1,964	3.19%	74	2.96%	-0.23%
North Dakota	156	0.25%	7	0.28%	0.03%
Ohio	2,155	3.50%	74	2.96%	-0.54%
Oklahoma	795	1.29%	36	1.44%	0.15%
Oregon	606	0.98%	22	0.88%	-0.10%
Pennsylvania	2,837	4.60%	111	4.44%	-0.16%
Rhode Island	187	0.30%	5	0.20%	-0.10%
South Carolina	1,057	1.72%	52	2.08%	0.36%
South Dakota	189	0.31%	10	0.40%	0.09%
Tennessee	1,508	2.45%	73	2.92%	0.47%
Texas	4,589	7.45%	186	7.44%	-0.01%
Utah	469	0.76%	18	0.72%	-0.04%
Vermont	132	0.21%	5	0.20%	-0.01%
Virginia	1,501	2.44%	49	1.96%	-0.48%
Washington	1,118	1.81%	45	1.80%	-0.01%
West Virginia	536	0.87%	20	0.80%	-0.07%
Wisconsin	984	1.60%	33	1.32%	-0.28%
Wyoming	113	0.18%	6	0.24%	0.06%
Count of States = 51	61,629		2,500		