

Center for Medicaid and CHIP Services

Myers and Stauffer LC

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

June 28, 2012

Topics

- Welcome and Introductions
- Level of Reporting
- Data Sources
- Data Collection and Survey Process
- NADAC Calculation
- NADAC Updates
- NADAC Help Desk
- NADAC File

What is the NADAC?

National Average Drug Acquisition Cost (NADAC) is the national average invoice price that retail community pharmacies pay to acquire drug products.

Level of Reporting

- CMS covered outpatient prescription and over-the-counter drugs
- Specialty pharmacies will not be included in the survey at this time
- NADAC will be reported at the 11-digit National Drug Code (NDC) level
- One NADAC will be reported per NDC
 - Acquisition costs collected from independent and chain pharmacies will be averaged into a single NADAC

Level of Reporting

- NADAC will be calculated at the drug grouping and CMS drug category level
 - NDCs for drugs that are pharmaceutically equivalent (active ingredient, strength, dosage form, route of admin) will be grouped together
 - NDCs classified as either single source (S), innovator multiple source (I) or non-innovator multiple source (N)
- Separate NADACs calculated for S/I drugs and N drugs
- NADACs will be applied to NDCs according to their S/I/N status on the CMS file

Level of Reporting (cont.)

Example 1 – Single Source Drug

Drug Grouping	NDC	Drug Category	NADAC
Crestor 10mg tablet	xxxxx-xxxx-x1	S/I	2.00000
Crestor 10mg tablet	xxxxx-xxxx-x2	S/I	2.00000

Level of Reporting (cont.)

Example 2 – Innovator Multiple Source Drug

Drug Grouping	NDC	Drug Category	NADAC
Lipitor 10mg tablet	XXXXX-XXXX-X3	S/I	2.00000
Lipitor 10mg tablet	XXXXX-XXXX-X4	S/I	2.00000

Level of Reporting (cont.)

Example 3 – Non-Innovator Multiple Source Drug

Drug Grouping	NDC	Drug Category	NADAC
atorvastatin 10mg tablet	xxxxx-xxxx-x5	N	1.00000
atorvastatin 10mg tablet	xxxxx-xxxx-x6	N	1.00000

Level of Reporting (cont.)

- In cases where the S/I/N designation for a NDC does not correspond with the brand/generic designation commonly used by States for reimbursement purposes, an override process is being developed
- 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
- CMS will review and approve proposed overrides

Data Sources

- CMS covered outpatient drug product file from Medicaid.gov
- National pharmacy compendia file used to identify individual pharmacy characteristics and sampling population
- Pharmacy drug acquisition costs collected through monthly surveys of invoice pricing
- Multiple national drug compendia for:
 - NDC validation
 - Drug name, strength, dosage form, package size, billing unit
 - Medicaid drug rebate DESI code
 - Published pricing data

Survey and Data Collection Processes

- Monthly national survey – all 50 states and the District of Columbia
- Random sample of 2,000 – 2,500 pharmacy stores per month
- Independent and Chain pharmacies (excludes specialty pharmacies)
- Voluntary submissions
- Requesting drug invoice purchase records from previous month

Survey and Data Collection Processes (cont.)

- Invoice records should contain NDC, unit purchase price paid, invoice purchase date, quantity purchased
- Survey request letters will be sent to arrive on or about the first day of each month
- Chains may request that all surveys be sent to a corporate contact and via email only
- Pharmacies are asked to respond within 2 weeks
- Reminder notices will be sent following initial mailing

Survey and Data Collection Processes (cont.)

- Invoice records may be sent in electronic or hard copy format
- Email, fax or mail is acceptable
- Invoice records will not be returned so pharmacies should send copies
- If pharmacy submits records voluntarily and identifies information as confidential, the information will not be disclosed except as required by law
- Information that is published will not include identifiable data to an individual or chain pharmacy

Survey and Data Collection Processes (cont.)

- Pharmacy submissions are tracked in a receipt log
 - Response rates
 - Independent and chain representation
- Data are preliminarily reviewed to determine completeness and reasonableness of data
- Data is entered or loaded into database
- Quality assurance procedures are applied (e.g., valid and active NDCs, costs do not equal AWP, etc.)
- Data submitted will remain under the control of CMS
- Electronic and hard copies are stored securely



Center for Medicaid and CHIP Services

JW1e I, 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.

Over--+

Pharmacy Owner/Manager

June 1, 2012

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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



Center for Medicaid and CHIP Services

National Average Drug Acquisition Cost (NADAC) Survey Rquest 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 L.C. Please do not include any invoices that include Public Health Services 340B drug pricing.

Over--.

June 1, 2012

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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

survcv@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 Office, 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 Cmmseors Row, Suite 200
Indianapolis, IN 46240-6419

OR

317-816-4134 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.

NADAC Calculation

- Data should be from surveyed pharmacies
- Data should be for valid and active NDCs
- Data should be for the calendar month under review
- NDCs should be on CMS covered outpatient drug product file or approved for inclusion by CMS (newly available covered outpatient drugs)
- NDCs should not have a DESI code of 5 or 6
- Only one NDC cost observation for each pharmacy is included – the most recent observation within survey period

NADAC Calculation (cont.)

Outliers

- Cost observations greater than +/- two standard deviations from the mean are removed
- A manual drug-by-drug group review is also completed and additional outliers are removed (e.g., obvious outliers, erroneous data, etc.)
- Manual review process supported through use of statistical tools

NADAC Calculation (cont.)

Calculations

- Cost data are compiled and summarized for each individual drug group
- S/I drugs that experienced price changes after the invoice date will be adjusted based on the relative change in its published drug prices
- Unit cost for each reported NDC within the individual drug group is arrayed from highest to lowest
- The number of pharmacies that purchased the NDC at the same unit cost is determined
- The NADAC average acquisition cost per unit is calculated

NADAC Calculation (cont.)

The table below illustrates how the average acquisition cost is calculated for an individual drug group.

SIMVASTATIN 20 MG TABLET

NDC	Drug Name	Generic Rating	Drug Package	Package Size (a)	Package Cost (b)	Unit Cost (c=b/ a)	Cost Observations (d)	Factor (e= c x d)
65862005290	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	8.96	0.09956	1	0.09956
68180047901	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	2.45	0.08167	9	0.73503
65862005290	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	6.12	0.06800	1	0.06800
16714068301	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	2.00	0.06667	1	0.06667
55111019905	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	31.66	0.06332	3	0.18996
55111019990	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	5.69	0.06322	1	0.06322
16714068301	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	1.77	0.05900	1	0.05900
16714068302	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	4.06	0.04511	3	0.13533
68180047902	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.82	0.04244	5	0.21220
68382006716	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.77	0.04189	1	0.04189
68382006716	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.52	0.03911	6	0.23466
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	38.56	0.03856	1	0.03856
16714068303	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	37.54	0.03754	1	0.03754
68180047902	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.37	0.03744	1	0.03744
68382006716	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.34	0.03711	1	0.03711
16714068302	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.27	0.03633	1	0.03633
16729000515	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.27	0.03633	1	0.03633
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	35.76	0.03576	2	0.07152
16714068303	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	35.39	0.03539	30	1.06170
68382006705	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	17.36	0.03472	4	0.13888
00093715456	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	1.04	0.03467	7	0.24269
55111019990	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.11	0.03456	1	0.03456
16714068303	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	34.33	0.03433	4	0.13732
55111019905	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	16.75	0.03350	1	0.03350
55111019905	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	16.42	0.03284	2	0.06568
16729000517	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	32.73	0.03273	1	0.03273
68382006710	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	31.48	0.03148	5	0.15740
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	31.44	0.03144	3	0.09432
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	30.93	0.03093	2	0.06186
16729000517	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	30.77	0.03077	1	0.03077
68382006710	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	30.36	0.03036	2	0.06072
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	28.05	0.02805	3	0.08415
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	27.32	0.02732	8	0.21856
00093715498	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	2.45	0.02722	41	1.11602
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	26.81	0.02681	3	0.08043
16729000515	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	2.25	0.02500	9	0.22500
55111019990	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	1.86	0.02067	3	0.06201
16729000517	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	19.60	0.01960	3	0.05880

Manufacturers in Sample
NDCs in Sample

7
16

All A-rated Generic Manufacturers
All A-rated Generic NDCs

17
47

173

6.19745

Average Acquisition Cost (e / d): 0.03582

NADAC Updates

Single Source or Innovator Multiple Source Drugs (S or I drugs)

- NADACs will be reviewed for updates on both a weekly and monthly schedule
 - Weekly due to changes in published prices (i.e., WAC)
 - Weekly due to inquiries into NADAC Help Desk
 - Monthly based on new survey data

NADAC Updates (cont.)

Single Source or Innovator Multiple Source Drugs (S or I drugs)

- Smoothing
 - Monthly average acquisition costs will be compared to existing NADAC
 - NADACs will be updated weekly for changes in published prices
 - Small percentage changes month-to-month likely do not reflect price changes but changes in the composition of the respondents
 - If the percentage change month-to-month is small, no change will be made to published NADAC. If percentage change is large, the NADAC will be revised

NADAC Updates (cont.)

Single Source or Innovator Multiple Source Drugs (S or I drugs)

- Percentage Change Threshold
 - For the top 500 brand drugs, there were 1,433 published price changes during the year
 - Only 8 published price changes were for 2% or less
 - Update/Revision Threshold: Change in average cost is greater than 2%

NADAC Updates (cont.)

Non-innovator Multiple Source Drugs (N drugs)

- NADACs will be reviewed for updates on both a weekly and monthly schedule
 - Weekly due to inquiries into NADAC Help Desk
 - Monthly based on new survey data
- Monthly based on new survey data
 - If an existing NADAC cannot be updated due to a lack of data from a subsequent monthly survey, the current NADAC drug will stay on the reference file until the sooner of 1) a month for which a new NADAC can be calculated, or 2) twelve (12) months from the initial NADAC date

NADAC Help Desk

- Staffed by certified pharmacy technicians, trained analysts and pharmacists
- Help Desk support is limited to:
 - Survey Support – questions related to the survey process, options for responding to survey, what information to submit, or other survey related questions
 - Drug price changes – notification of recent drug price increases not reflected in posted NADAC file
- Help Desk will not address pharmacy inquiries into specific State or claim reimbursement related questions or concerns

NADAC Help Desk (cont.)

- Drug Price Change Inquiries
 - Each inquiry will be researched and addressed in a timely fashion
 - Research will include comparison to costs collected through survey, confirmation of drug or material shortages, and confirmation of price changes with other community pharmacies
- Validated drug price changes will be reflected in weekly updates

NADAC Help Desk (cont.)

- Due to the expected volume, the results of individual pharmacy inquiries will not be communicated directly back to the pharmacy, but instead, if a change is confirmed it will be included in a weekly update
- Pharmacies may call back into the help desk to receive an update on the status of their inquiry if they are unclear of the resolution

NADAC File

- The NADAC file will be posted to the Medicaid.gov website on a weekly basis
- Each new file will be a full replacement of the previous file
- Meeting with compendia to discuss sample file layout and update processes

Questions / Comments

- For additional information or to submit questions or comments
 - Email: RPS@cms.hhs.gov
 - Website: <http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html>
- For those unable to attend this webinar, a taping of the presentation and related slides will be available on the website above for one week following the webinar.