NCPA Summary of Draft Methodology for Calculating NADAC

Introduction:
CMS has released "Draft Methodology for Calculating the NADAC – National Average Drug Acquisition Cost". The purpose of NADAC is to create a national price benchmark that is more reflective of the prices pharmacies pay to acquire prescription and over the counter drugs. NADAC will be based on a nationally distributed survey of retail pharmacies invoice price, both chains and independents. CMS has contracted with Myers and Stauffer, a nationally certified public accounting firm, to conduct and manage the survey.

Data Reporting:
NADAC will be calculated incorporating three main criteria; drug grouping, drug category and pharmacy type. This data will then be reported at the 11-digit NDC level.

- *Drug Grouping* will be based on active ingredients, strength, dosage form and route of administration. Drugs that are therapeutically and pharmaceutically equivalent will belong to the same grouping. The guidance does make exceptions for certain medications in particular cases.
- *Drug Category* will classify each NDC listed in the NADAC file as Single Source (S), Innovator multiple source (I) or Non-innovator multiple Source (N). In instances where this classification does not correspond with the manner in which the state classified a drug for reimbursement purpose CMS has detailed an override process.
- *Pharmacy Type* is the identification of a pharmacy as a chain or independent. There will be separate NADACs based on drug costs collected from different pharmacy types.

The Survey Process:
Acquisition cost data will be collected from a nationally random sample of 2,000-2,500 pharmacies per month. All retail pharmacies are eligible for selection each month, but statistically the chance of a pharmacy being selected more than once a year is less than 5%. Survey letters will be mailed to the pharmacy location requesting the *voluntary submission* of data from the previous month. Surveys can be mailed to a pharmacy or corporate contact in regards to chain pharmacies.

Data requested will involve: 11-digit NDC, unit price paid, invoice date and quantity purchased. This is the only data retained for use in calculating NADAC. Submission of this data will be accepted in hard copy or electronic format. Also, pharmacies may have their wholesaler produce this data and submit it on their behalf.

Specialty and 340B pharmacies will be excluded from the survey process at this time.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Confidentiality:
A document will be provided with all survey letters which requests the pharmacy's intention for submitted data to remain confidential. If not returned with the pharmacy's submitted data, Myers and Stauffer LC will attempt to contact the pharmacy to confirm the pharmacy's intent. A pharmacy's confidentiality status is tracked as data is acquired and reviewed. All survey responses will be stored in a secure and confidential manner. All information submitted is the property of CMS, and Myers and Staffer is prohibited from utilizing the data for any purpose other than directed by CMS

Processing Data:
Data will be reviewed by Myers and Stauffer to ensure costs entered reflect submitted data and the NDCs are valid. Drug prices that are found to be equal to or greater than AWP will not be entered into the database. Other quality assurance procedures will then be applied.

Calculating NADAC:
The NADAC will be calculated as the average of the per-pricing unit cost weighted by the submitted acquisition costs. CMS says NADAC will be a simple average of the sample of prices reported. Prior to calculation, data will be classified according to Drug Category and Pharmacy Type. Data are required to satisfy certain quality criteria. Quality criteria include requirements that the invoice data must be from the month and year request by CMS, data must be from a sampled retail pharmacy, and the drug product must not have a "less than effective" rating by the DESI, etc.

A minimum number of reported drug costs for each grouping/category are required to provide statistically significant results.

Cost data for single source (S) and innovator multiple source (I) products will be separated from non-innovator source (N) products for calculation.

Exceptions may need to be applied and in some instances a NADAC may need to be adjusted based on package size. Other exceptions may be for multiple innovator products that share the same active ingredients, strength, dosage form and route of administration, but differ significantly in per unit pricing.

NADAC Updates:
NADAC updates will occur on both weekly and monthly basis.

Non-Innovator multiple source drugs:
On a weekly basis, NADACs will be reviewed and adjusted as needed based on research initiated by inquiries to a Help Desk. If an update is required it will be updated in the next weekly reference file.

On a monthly basis, NADACs will be replaced with updated NADACs using the results of the ongoing monthly surveys. If an average drug cost cannot be calculated with data from a subsequent monthly survey, the existing NADAC will remain on the reference file until 1) a month for which a NADAC can be calculated; or 2) twelve months. After twelve months if a NADAC still cannot be recalculated it will be removed.

Single source of Innovator multiple source drugs:
On a weekly basis, NADACs for S/I drugs will be reviewed and adjusted as necessary based on analysis of published prices. Published prices are measured as the relative percentage difference between the new and previous price. Such updates can occur based on research initiated by pharmacy inquiries to the Help Desk.

On a monthly basis, NADACs will be updated using the results of the monthly surveys. Updates for "S" or "I" drugs will go through a comparison and smoothing process utilizing past data. Also, certain thresholds must be met to constitute the need for an update. Monthly updates of "S" or "I" drugs will need to fall within a reasonable threshold. For example, analysis differences of less than 2% may not warrant a change.

New Drugs:
There may be a lag between the availability of new drugs entering the marketplace and their inclusion on the NADAC file. Myers and Stauffer will receive interim updates, which will be reviewed on an individual basis.

Reference Files and Deliverables:
The reference file will be published as a text and Excel file containing: NDC, Drug Name, NADAC, Pharmacy Type, NADAC date, NDC attribute. This file will be posted on Medicaid.gov on a weekly basis. An accompanying narrative will be published as well. Monthly NADAC updates will be assigned the date that the NADAC file was sent to CMS from Myers and Stauffer. For weekly NADAC file updates the NADAC date will be updated accordingly as the weekly NADAC file date it as sent to CMS.