

National Average Drug Acquisition Cost (NADAC) Questions and Responses

Topic Category	Comment/Question	Response
1. NADAC	Why has CMS invested the resources to calculate a NADAC?	<p>CMS anticipates that the NADAC files will give state Medicaid agencies covered outpatient drug information regarding retail prices for prescription drugs. State Medicaid agencies will be able to use this information to evaluate their own pricing methodologies and compare payments to those derived from this survey.</p> <p>For additional information regarding the Survey of Retail Prices, including the NADAC, please see our Survey of Retail Prices webpage at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html</p>
2. NADAC	Why would CMS invest to survey pharmacies to collect invoice costs when pharmacies include this information on submitted claims?	<p>CMS has developed the National Average Retail Price (NARP) and the NADAC to obtain ingredient cost information, along with information concerning retail survey price information. Pharmacy invoice prices available from surveyed pharmacies and the voluntarily supplied invoices provide documentation of the actual covered outpatient drug purchases. In addition, the majority of pharmacies do not submit invoice costs on pharmacy claims.</p> <p>CMS is also responsible for submitting a report to Congress, which includes pricing information on ingredient costs, rebates, and pricing trends.</p> <p>For additional information regarding the Survey of Retail Prices, please see our Survey of Retail Prices webpage at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html</p>
3. NADAC	The NADAC will be updated weekly - will it be published weekly as well?	<p>Yes, we plan to continue publishing it on our website at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html</p>
4. NADAC	Does CMS anticipate the availability of daily NADAC updates in the future?	Not at this time.

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5. NADAC	Will the NADAC be published on a site that is available to anyone?	Yes. It is currently published at the following website: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
6. NADAC	When did CMS start sharing the draft NADAC files prior to finalizing them?	The first draft file became available in October 2012. Draft files have been published on a weekly basis since then.
7. NADAC	If NADACs will be updated weekly based on new pricing information and help desk calls, how will states be notified of such reviews/adjustments? What guidance will be offered to the states on implementation of pricing changes?	<p>The files will be published weekly with all changes noted at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html and available to the states. Information regarding pricing changes is available in the NADAC methodology document on Medicaid.gov.</p> <p>Even though the states will determine how the NADACs will be used in each of their respective Medicaid programs, each 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. CMS will be available to answer questions in order to ensure that the states understand the information shared in the file.</p>
8. NADAC	In what format will the NADAC file be posted?	Excel
9. NADAC	Can you provide clarification on drug groupings - when will the NADAC be broken down by package sizes?	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'.
10. NADAC	CMS should consider developing regional price calculations to account for any variations in regional wholesaler pricing to independent pharmacies.	Regional price variations will be reviewed and analyzed on an on-going basis. To date, we have not noted any significant price differentials on a regional basis.
11. NADAC	Will a separate NADAC be calculated for chain and independent stores?	Not at this time.

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12. NADAC	What is the rationale for calculating separate NADACs from S/I drugs (brand) and for N (generic) drugs?	Separate NADACs are needed to assist State Medicaid agencies in assessing reimbursement rates for brand and generic drugs. For example, Medicaid programs often use a separate reimbursement rate for brand drugs when a multiple source brand is preferred on the preferred drug list (PDL) or if the prescription is written as “brand medically necessary”.
13. NADAC	Describe the rationale for the S/I/N override process?	Please refer to explanation code 6 from the NADAC Data Field Definitions document at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html . Code 6 signifies that 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 Covered Outpatient File designation.

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14. NADAC	How does the override process (assignment of S/I/N or brand, generic) affect a state's reimbursement? Will states be required to reconcile previous reimbursement to match the overrides?	<p>States may have different policies for the brand or generic designations when determining reimbursement for certain drugs, such as drugs that are generally recognized and sold as a brand, but are in fact a branded generic that has been approved by the FDA under an ANDA. These drugs are designated on the NADAC file as B-ANDA.</p> <p>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.</p> <p>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 the NADAC methodology document found at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html.</p> <p>States must submit a state plan amendment in accordance with state plan requirements if they decide to use NADACs as a basis for payment.</p>
15. NADAC	Please clarify the minimum number of observations to set a rate - in general, and also regionally and by pharmacy type. CMS should explicitly state what constitutes a valid sample. What confidence interval and confidence level will be required?	<p>A minimum number of NDCs with price information necessary to calculate a rate has not been formally established, but will never be less than five observations. The number of observations necessary to obtain estimates with reasonable precision depends on the pricing variations submitted. From the initial analysis of the invoice data received, it was found that the standard deviation for acquisition costs are relatively small, so even with as few as five cost observations, a NADAC can be calculated with a reasonable level of precision. Findings from these analyses also demonstrate that the mean unit cost for brand and generic drug NADACs have an average margin of error of 0.5% and 2.4% respectively, at a 95% confidence level. Therefore, the confidence interval encompasses the true mean unit cost 95 out of 100 times.</p>

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16. NADAC	Regarding the one cost observation per NDC per pharmacy- why would the lowest cost be used to calculate a rate? Why not count all costs from a particular pharmacy or average them?	<p>The most recent cost observation within the survey period will be utilized in the rate calculation, not the lowest. The most recent cost is included to ensure that the most up to date costs are included in rate setting. This addresses such things as mid-month price changes (increases and decreases).</p> <p>However, if there are 2 cost observations reported on the same day, and these are the most recent cost observations, the lowest cost is included since the drug is available to be purchased at that rate.</p>
17. NADAC	NADAC will be weighted by the submitted acquisition costs - what is the definition of weighted? How will CMS assure there is adequate representation used from independent pharmacies?	The NADAC is not weighted, but a simple average of the acquisition costs collected. No adjustment will be made to the rates based upon chain vs. independent pharmacy types since the relative impact of the differences in acquisition costs between a chain and independent pharmacy is minimal based on experience with the draft NADACs.
18. NADAC	Is the two standard deviation outlier removal process the most appropriate metric?	Yes. Several outlier removal processes have been examined by statisticians. We have found, based on our prior experience with the draft NADAC files, that the two standard deviation approach combined with a manual review is the most effective process for removing outliers.
19. NADAC	Will CMS publish both a brand (S/I) and generic (N) price for innovator multi source drugs to ensure that a NADAC is available when a restrictive prescription is written?	Yes, a separate NADAC will be available for the innovator multiple source NDC and its corresponding generic provided that enough cost observations are collected to establish a NADAC price.
20. NADAC	How does CMS intend to develop a NADAC for drugs where invoice data has not been made available for any NDCs in the drug group?	<p>NADACs will only be calculated where drug group acquisition cost data is available through the monthly survey process. If cost data is not sufficient to update an existing NADAC, the rate can carry over for up to 12 months and then will be removed from the file. All covered outpatient drug NDCs will not have a NADAC.</p> <p>Based upon the initial analysis, a NADAC will be available for 93% of brand and 97% of generic Medicaid claim submissions.</p>

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21. NADAC	How does CMS intend to publish a NADAC for drugs when invoice data is not available during the current collection period for any NDC in a given drug group?	Acquisition cost data will have to be collected for drug groups in order to calculate an initial NADAC for applicable NDCs within the drug group. If invoice data is not collected in subsequent collection periods, then a NADAC for a prior period can carry forward for up to 12 months. If invoice data is not sufficient with enough cost observations to update the NADAC after 12 months, the rate will be removed from the file.
22. NADAC	How will CMS address NADACs for OTCs and prescription drugs with a Universal Product Code (UPC) or Health Related Item (HRI)?	Only products that meet the definition of covered outpatient drugs with an NDC number will receive a NADAC price. 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 receiving a NADAC price
23. NADAC	Please define the "drug by drug" review for "reasonableness" process.	<p>Each drug group for which a NADAC has been calculated undergoes a comprehensive review prior to a NADAC being assigned and published. This comprehensive review, which is designed to address submissions as well as NADAC calculations, is performed by a review team comprised of analysts, accountants and pharmacists.</p> <p>The array of invoice prices 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 draft NADAC calculation. In addition, this review is conducted to ensure that obvious outliers, potential data entry/data import errors and package size discrepancies have been addressed.</p>
24. NADAC	It may be problematic to remove drug pricing that exceeds AWP. This may indicate that a reconsideration of the AWP is warranted or that there is a drug shortage.	Drug prices that exceed AWP are not removed. When a pharmacy submits data, a quality assurance check is done to ensure that invoice prices are being reported and not being substituted with commercial pricing benchmarks such as the AWP. At this point, the percentage of prices reported that are equal to or greater than AWP are calculated. If these prices are equal to or above AWP, further investigation (such as a determination of drug shortages) is initiated to ensure the correct data is submitted.

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25. NADAC	The methodology document states that obsolete NDCs would not be included in the rate setting calculation. Since obsolete and CMS termination dates can be several years apart, wouldn't CMS termination date be the better determinant on whether an NDC should be used in rate setting?	Neither terminated NDCs reported to CMS nor obsolete NDCs will be included in the NADAC calculation.
26. NADAC	Creams and ointments were noted as having separate rates for package sizes. Should unit dose products be separated from bottle packaged products for NADAC purposes?	Unit dose packaging for tablets and capsules will not have different NADACs.
27. NADAC	Will drugs not typically sold in retail community pharmacies, such as 5i drugs, be eligible for a NADAC?	All products that meet the definition of covered outpatient drugs with an NDC number collected through the survey are eligible for a NADAC. The NDCs currently collected are limited to those purchased by retail community pharmacies.
28. NADAC	CMS states that the assignment of a NADAC does not constitute the status of the NDC as a covered outpatient drug. Why would a NADAC be assigned to a non-covered outpatient drug?	The objective is to only calculate a NADAC for covered outpatient drugs with an NDC number. However, the NADAC file is not intended to be utilized as a coverage reference file. This statement deals with timing issues as drug products are added and terminated from the covered outpatient drug list.
29. NADAC	CMS needs to develop and publish a methodology that explains what justifies a weekly change in rates.	CMS posts a complete file replacement weekly on Medicaid.gov which includes any pricing changes that have occurred in the past week. The rationale for weekly updates to NADAC rates, such as for interim (weekly) price changes within the monthly survey period, are included in the draft NADAC methodology document located at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
30. NADAC	What happens if prices increase but CMS does not collect enough cost observations to adjust a new NADAC?	Pharmacies can contact the help desk via phone or e-mail to initiate a NADAC review. The toll free help desk phone number is 855-457-5264 and the e-mail address is info@mslcrps.com .

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31. NADAC	How many pharmacy inquiries are needed to justify a price change?	Each inquiry is sufficient to initiate a review, and if needed, a change will be made to the respective published NADAC. The help desk will investigate a price change with additional pharmacy providers.
32. NADAC	What compendia and pricing measures will be used for weekly updates?	The primary basis for weekly updates for S/I (brand) product NADACs will be the wholesale acquisition cost (WAC). The updates will be based on wholesale acquisition costs obtained from compendia sources.
33. NADAC	Why would CMS collect monthly survey data if weekly updates due to published pricing and pharmacy inquiries can override NADAC values?	Monthly survey data is the primary basis for establishing the NADAC rates. Weekly updates will only be used to update NADACs previously established based upon collected monthly survey data. The NADAC established from survey data will be recalculated each month with each new set of applicable survey pricing observations.
34. NADAC	Two percent variance requirements for updates may represent a monetary value which could be too large. Please provide the rationale for this threshold. Also discuss the expected frequency of price changes below this threshold from the state surveys.	The 2% variance threshold for S/I (brand) drugs was established after analysis of the published prices and based on the contractor's experience with state programs. Published pricing changes are already accounted for in the weekly NADAC update processes and the increases are very rarely less than 2%.
35. NADAC	Will the NADACs be statistically reliable?	Based on our experience with the draft files, the information has been found to be statistically reliable. Please refer to the statistical summaries presented during the NADAC portion of the Overview of Reference File Results presentation. This presentation is available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html

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36. NADAC	Will a statistically significant response regarding geographic distribution be considered to ensure accuracy of calculating the NADAC?	<p>The NADAC will be calculated as a national average. Based on our contractor's state program experience and previous results in surveying pharmacies, we do not expect that NADACs will vary based upon regional or geographic distributions. Statistical geographic considerations were presented during the NADAC portion of the Overview of Reference File Results presentation. This presentation is available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html</p>
37. NADAC	Would it be possible for rate updates due to help desk calls to be dated the day of the call instead of the date of the file to CMS?	<p>The date of the rate update as a result of a help desk call will be the date that CMS publishes the file. The NADAC rate updates will be published on a weekly basis based on research and validation of the help desk inquiry.</p>
38. NADAC	How will NADACs that are adjusted due to help desk calls be calculated?	<p>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.</p>
39. NADAC	CMS needs to develop an appeals process for a pharmacy that can document that its invoice acquisition price is above the NADAC within the published time frame.	<p>The help desk is available for inquiries of this nature.</p>
40. NADAC	If a NADAC is updated due to published pricing, when will the NADAC be updated based solely on survey responses?	<p>The NADAC will be updated based on pricing observations with the next monthly survey period.</p>
41. NADAC	Please estimate the level of bias created as a result of including rebates in some cases and not in others.	<p>There is no bias with the design when collecting pricing information. The NADAC is an objective collection of prices as reflected on the invoice. It does not account for off-invoice rebates, discounts or price concessions.</p>

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42. NADAC	How is chain vs. independent defined?	For purposes of calculating the NADAC, CMS defines a chain pharmacy 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 a pharmacy that is not owned or operated by a chain. Franchise pharmacies are classified as independent pharmacies.
43. NADAC	Why did CMS decide to have one NADAC when it is known that costs can vary considerably between chain and independent pharmacies?	This decision was based on actual invoice data collected and analyzed during the initial NADAC surveys beginning in June 2012. Based on those surveys, we determined that chain and independent pharmacies have similar average acquisition costs for covered outpatient drugs and did not vary considerably. Chain and independent acquisition cost, survey response and overall survey composition were discussed in detail during the results webinar. The webinar slides are located at: http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
44. NADAC	We recommend that CMS clarify the "age" of the NADAC data when it is published. It appears the data may be as much as 90 days old. If it is used in calculating pricing it should be near real time but no more than one week in arrears.	While the age of the data used to set rates is not included on the published file, the effective date has been added to indicate the latest rate update. While this is not real time invoice data, the file is updated weekly as changes occur. Please refer to the draft NADAC explanation code definitions for additional information. These codes clarify the basis for the NADAC calculation. These definitions are located at: http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
45. NADAC	CMS needs to include off-invoice price concessions in the survey or rename the NADAC to reflect an invoice cost rather than acquisition cost.	CMS is considering plans to develop a survey to collect and monitor off-invoice discount data. We expect that this data will be used to monitor the stability of these discounts and their relationship to acquisition costs to help establish the effect of off-invoice concessions.

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46. NADAC	Will there be an attempt to calculate a NADAC for drugs that are not generally distributed through retail community pharmacies but instead are distributed through hospitals or clinics?	Not at this time.
47. NADAC	How often will the off invoice survey be conducted and how will the data be used?	We anticipate that the off-invoice survey will be conducted on an annual basis. We anticipate using the information obtained in the off-invoice survey to monitor to what extent off invoice rebate, discounts and other price reductions affect the invoice pricing.
48. NADAC	What if the wholesaler is unwilling to provide data?	This concern was voiced during the initial survey and CMS has worked with the wholesalers to facilitate their participation. Regardless of whether wholesalers choose to provide data, pharmacies have the option to submit copies of invoices.
49. NADAC	How will CMS determine if there is selection bias for a survey and if so, how will they correct for such bias?	The survey is drawn from a random sample of approximately 63,000 pharmacies nationwide. Selection bias, draft NADAC response and overall survey composition were discussed in detail during the results webinar. The webinar slides are located at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
50. NADAC	Will CMS publish a survey schedule with detailed mailing dates, cut off of data collection, NADAC calculation and publication of the monthly NADACs?	At this time, we have not decided to publish a survey schedule; however, we will take this request under consideration.
51. NADAC	What is the definition of specialty pharmacies and why are they excluded from the survey process?	For purposes of the NADAC calculation, pharmacies are currently identified as a specialty pharmacy through self-reporting. The NADAC survey is currently limited to Retail Community Pharmacies.

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52. NADAC	How will CMS verify that 340B pharmacies and other providers with special pricing are not included in the survey?	The NADAC survey instrument instructs participating pharmacies not to include Public Health Services 340B pricing. In the case that 340B pharmacy pricing is submitted and able to be identified, it will be excluded from rate setting. 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.
53. NADAC	The sample will be distributed across all pharmacy types in all states. How do you intend to ensure submissions follow the same pattern?	Since the submission of the survey responses is voluntary, submission responses may not correspond to the sample composition. Draft NADAC response and overall composition were discussed in detail during the December 5, 2012 results webinar. The webinar slides are located at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
54. NADAC	The survey instrument says collection should be for drug ingredient costs only but some invoices may include shipping, warehousing and administrative costs. Pharmacies submitting these invoices could be accused of making false statements to increase NADAC values and should receive liability protection if they are making a good faith effort to provide cost information.	Additional costs included on the invoice, such as shipping, warehousing and administrative costs will not be utilized when calculating the NADAC. Pharmacies are asked to submit copies of invoices and are not responsible for deleting references in those invoices to shipping, warehousing and administrative costs.
55. NADAC	If rebates and discounts are not collected, how will manipulation similar to the AWP be prevented?	We anticipate that the off-invoice survey will be conducted on an annual basis to collect information regarding rebate and discounts. We anticipate using the information obtained in the off-invoice survey to monitor pricing on the pharmacy invoices and to what extent off-invoice rebate, discounts and other price reductions affect the invoice pricing. We expect that the data could be used to provide additional information about the stability of these discounts and their relationship to acquisition prices.

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56. NADAC	Since Myers and Stauffer LC is conducting AAC studies in other state programs, it is possible that data collected for CMS could be shared with other government entities in spite of the confidentiality requirements under the CMS contract. CMS should publish a draft of the controls being used to prevent this from occurring.	Myers and Stauffer LC collects, stores, and processes data collected for the NADAC on a server dedicated exclusively for the CMS contract. The NADAC acquisition cost data is not intermingled with data collected for other state contracts and the contractor is prohibited by the terms of the contract from sharing this data outside of use for the NADAC to CMS.
57. NADAC	What is the response rate for the pharmacy survey?	To date, an average of 500-600 pharmacies are voluntarily participating each month.
58. NADAC	Is the survey limited to certain drugs?	The NADAC survey is currently limited to collection of covered outpatient drug invoices from Retail Community Pharmacies.
59. NADAC	Is it possible to include a unit of measure in the file format?	Yes, the unit of measure has been added to the NADAC file.
60. NADAC	Will there be a valid values table with these reports?	Yes, there is a NADAC data definitions file posted on the web site. The files are posted in Excel so the file can be formatted for importation into a database.
61. NADAC	What happens when an NDC has an 'incorrect' grouping for brand and generic and therefore an 'incorrect' rate is applied?	Approximately 95% of the NADACs are calculated according to the CMS covered outpatient drug file drug category codes. S/I (single-source / innovator multiple source) drugs are grouped as brands and N (non-innovator) drugs are grouped as generics in pharmaceutically equivalent drug rate setting groups. Occasionally the CMS designations for NADAC are overridden by the state for purposes as described in the methodology document at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html .
62. NADAC	Are there any plans to post the NADAC by GPI (Generic Product Indicator)?	No. GPI is a proprietary field provided by a drug compendium provider. CMS offers transparency into the NADAC calculation process by posting these rates at the NDC level.

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63. NADAC	63,000 pharmacies are being surveyed but only 600-800 pharmacies are responding. Is this an adequate response rate?	Of the approximately 63,000 retail community pharmacies in the United States, a random sample of these pharmacies is surveyed monthly. The current response rate of 500-600 pharmacies is more than adequate for establishing statistically sound NADACs. Please refer to the statistical summaries presented during the NADAC portion of the Overview of Reference File Results presentation. This presentation is available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
64. NADAC	Invoices are showing WAC rates but manufacturers have said that WAC is not the amount paid by many or all customers.	For the majority of invoices, the invoice acquisition price is not equal to WAC.
65. NADAC	Will the NADACs calculated for a drug group be extrapolated to all NDCs within that drug group regardless of whether costs were collected for that NDC and whether or not the NDC is on the CMS covered outpatient drug list?	The NADAC is calculated using acquisition cost data for all CMS covered outpatient NDCs within a drug group. Once a NADAC is set for a drug group, the NADAC will be applied for NDCs included in the Medicaid Drug Rebate (MDR) covered outpatient drug list. NADACs will be calculated regardless of whether or not prices 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.
66. NADAC	The draft methodology indicates that obsolete NDCs will be excluded from NADAC calculations. Will CMS continue to publish obsolete NDCs with the last valid NADAC? If so, how long will it remain in the reference file?	NDCs that are obsolete (no longer manufactured) are excluded from NADAC calculations. These NDCs will be published in the reference file with the NADAC applicable to their associated drug product group up until the date that the NDC is terminated from the CMS covered outpatient drug file or until the associated CMS Termination Date (defined as the manufacturer reported date that the last lot expires).

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67. NADAC	<p>Myers & Stauffer LC indicated during the webinar that it was receiving 600-800 survey responses per month; this appears to represent only a quarter to a third of the 2,000 – 2,500 pharmacies that CMS said it would survey monthly, and only 1% of the more than 60,000 chain and independent pharmacies nationwide. CMS should publish for comment the criteria used in determining when survey responses are deemed sufficient to calculate a NADAC, and CMS should not publish NADACs without sufficient current survey responses.</p>	<p>The monthly survey is a random sample drawn from approximately 63,000 pharmacies nationwide with an average of 500-600 pharmacies responding each month. Based on Myers and Stauffer's experience with the program, the response rate is adequate to ensure statistical validity for the established NADACs. Draft NADAC response, overall survey composition and NADAC simple vs. weighted averages were discussed in detail during the results webinar. The webinar slides are located at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html</p>
68. NADAC	<p>CMS should publish for public review and comment the criteria which Myers & Stauffer is using to determine when there are sufficient responses to publish a NADAC for a particular drug, as well as any related data on the statistical reliability of NADACs determined using such criteria. Is one purchase from a single pharmacy enough to set a NADAC?</p>	<p>A minimum number of NDCs with price information necessary to calculate a rate has not been formally established, but will never be less than five observations. The number of observations necessary to obtain estimates with reasonable precision depends on the pricing variations submitted. From the initial analysis of the invoice data received, it was found that the standard deviation for acquisition costs are relatively small, so even with as few as five cost observations, a NADAC can be calculated with a reasonable level of precision. Findings from these analyses also demonstrate that the mean unit cost for brand and generic drug NADACs have an average margin of error of 0.5% and 2.4% respectively, at a 95% confidence level. Therefore, the confidence interval encompasses the true mean unit cost 95 out of 100 times.</p>

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<p>69. NADAC</p>	<p>Myers & Stauffer also noted that, as indicated in the draft NADAC methodology, a NADAC may be published for one month based upon receipt of sufficient survey responses, and if sufficient survey responses are not received to publish a new NADAC, the original NADAC will continue to be published for up to 12 months. We continue to believe that this is a fundamentally flawed approach. Publishing a “current” NADAC without current survey data is inherently misleading and inaccurate, particularly for “N” drugs which are not monitored for WAC changes.</p>	<p>Acquisition cost data must be collected for drug groups in order to calculate an initial NADAC for applicable NDCs within the drug group. If invoice data is not collected in subsequent collection periods, then a NADAC can carry forward for up to 12 months. Drug groups that typically do not get updated monthly are those drug groups with NDCs which have low utilization.</p> <p>Based on several months of draft NADAC rate experience, 85% of generic rate groups are updated each month based upon new survey data. On a quarterly basis, this figure increases to 93%. For the small number of NDCs where pricing data is not sufficient to update the NADAC for 12 months, the rate will be removed from the file.</p> <p>The Wholesale Acquisition Cost (WAC) is used to update brand drug prices on a weekly basis; however, the WAC does not consistently correlate to acquisition costs for generic drugs and is not available for all generic drugs. Although, N (generic) drugs are not monitored for WAC changes, pharmacies have the option to contact the help desk via phone or e-mail to initiate a NADAC review. The toll free help desk phone number is 855-457-5264 and the e-mail address is info@mslcrps.com.</p> <p>Additionally, we will continue to consider this issue, especially if we receive a number of help desk requests/comments on it.</p>

Topic Category	Comment/Question	Response
70. NADAC	While pharmacies will be able to contact a help desk to seek a pricing change if they believe the published NADAC is inaccurate, there is no assurance that current, accurate NADACs will in fact be published based upon such submissions. Making such submissions frequently may not be worth a pharmacy's time and effort. Is an invoice submission from a single pharmacy enough for Myers & Stauffer LC to establish a new NADAC? Here again, CMS should publish for comment the criteria (statistical and otherwise) that Myers & Stauffer LC will apply in determining whether to establish a new NADAC based upon help desk submissions.	Myers and Stauffer LC has utilized identical help desk processes and procedures in multiple states for supporting acquisition cost based reimbursement models. Based on over a decade of experience providing help desk services for Maximum Allowable Cost (MAC) programs, Myers and Stauffer, LC has refined their help desk program to review pharmacy inquiries and quickly implement substantiated changes in reimbursement rates. Several years of practical experience indicate that pharmacies readily utilize this process to communicate changes or concerns with drug pricing. A single pharmacy inquiry will initiate the investigation of a given NADAC. The help desk will confirm price changes with the inquiring pharmacy and with additional pharmacy providers. The NADAC will then be adjusted accordingly, if appropriate, based upon the rate review.
71. NADAC	Can manufacturers contact the NADAC help desk if they have questions regarding a specific NADAC rate?	Yes
72. NADAC	Will the monthly state level average acquisition cost data by pharmacy type be available for public consumption and research?	The NADAC will be published as national average acquisition cost data. Individual state data will not be made available.
73. NADAC	If the goal of the NADAC is to arrive at a national average price that retail pharmacies pay to wholesalers to acquire a drug, was the alternative of surveying wholesalers directly for their selling prices considered?	Yes, this was considered. However, we have found that wholesalers will often not release such purchase information. Surveyed pharmacies have the option to work directly with their respective wholesaler(s) to supply invoices to Myers and Stauffer, LC.
74. NADAC	Are there any plans to survey mail order pharmacies for the NADAC?	Not at this time.
75. NADAC	Are previously posted NADAC files available for download?	CMS has posted draft archive NADAC files at: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html .

Topic Category	Comment/Question	Response
76. NADAC	During the results webinar it was stated that CMS was supplying Myers and Stauffer, LC with weekly additions to the covered outpatient drug file. Will the weekly NDC additions be made available to the public?	CMS publishes a Medicaid Drug Rebate file quarterly on the CMS website. Myers and Stauffer, LC uses the weekly additions to the database that are received from CMS for purposes of calculating and publishing the NADACs. As a new covered outpatient drug receives a NADAC price, it is included in the weekly NADAC pricing files, but is not identified as a new addition.
77. NADAC	Does CMS have the authority to collect or publish the requested data?	The Medicaid drug rebate provisions provide broad authority for CMS to survey and collect information regarding covered outpatient drug prices. CMS is also responsible for submitting a report to Congress, which includes information on ingredient costs, rebates, and pricing trends.
78. NADAC	CMS should explicitly state that the states may not use the NADAC for reimbursement unless dispensing fees are also adjusted appropriately.	CMS is issuing these NADAC files to make information available to the states. We recognize that pharmacy providers should be reimbursed adequately for their professional services and if states choose to revise their reimbursement methodology to use NADAC as a basis for payment, they must submit a state plan amendment (SPA). States should also consider whether their current dispensing fee continues to provide adequate reimbursement for the cost of dispensing a prescription to a Medicaid beneficiary, as well as the need to submit a SPA.
79. NADAC	If a state decides to use the NADACs, they should have to use it for all providers and all drugs with a NADAC.	The NADACs are available to the states, but this document does not address how states may use this data. As previously noted, a state may assess and consider the use of NADACs as a basis for payment. States must submit a state plan amendment in accordance with the state plan requirements if it decides to use NADACs as a basis for payment to pharmacy providers.
80. NADAC	Will the states be required to use the NADAC file as updated weekly; not to be able to underpay using only the monthly updates?	There are no mandatory requirements for the use of any of this data by states.

Topic Category	Comment/Question	Response
81. NADAC	Will states have to submit a State Plan Amendment before using the NADAC?	Yes. A state must submit a SPA in accordance with the state plan requirements if it decides to use NADAC a basis for payment
82. NADAC	Can all surveys be considered confidential even without the cover sheet?	A cover sheet should be submitted with all survey invoice data; however, all proprietary information from these voluntary surveys is considered confidential.
83. NADAC	If confidentiality is not requested, how, with whom and to what degree is the information shared with the general public?	No information will be shared with the general public that identifies any individual pharmacy.
84. NADAC	Please provide greater details on oversight over documents and other confidentiality concerns - limiting use of data, clarification of Federal records requirements and provisions for destruction.	Please review the NADAC methodology document that supplies this information in detail at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NADACDraftMethodology.pdf
85. NADAC	Could CMS transfer the invoices to other government agencies such as the OIG or DOJ? Or will the invoices be held by the contractor and used only for NADAC calculations?	These invoices are not available to other government agencies unless authorized or required by law. The invoices are only being used for NADAC calculation purposes.
86. NADAC	Can CMS clarify what the federal retention period will be and also who will have access to these records?	These records are held confidential and will not be disclosed, except as authorized or required by law.
87. NADAC	CMS should explicitly specify that states choosing to utilize NADAC data for purposes of reimbursement must utilize it exclusively for all products and all providers that have a current NADAC value.	We are not requiring that states use NADAC prices in their pharmacy reimbursement methodologies. However, the NADAC files will give state Medicaid agencies information regarding average drug acquisition costs for covered outpatient drugs.

Topic Category	Comment/Question	Response
88. NADAC	CMS should require that states utilizing NADAC put in place strategies to assure optimal outcomes for patients through patient care services which include but are not limited to medication reviews, patient education and counseling, disease screening, referral.	We expect states to address such patient care services regardless of the payment methodology they choose.
89. NADAC	CMS should instruct states not to use NADACs in non-pharmacy settings.	<p>We are not instructing or requiring that states use NADAC prices in their pharmacy reimbursement methodologies. However, the NADAC files will give state Medicaid agencies information regarding average drug acquisition costs for covered outpatient drugs for them to consider.</p> <p>Regardless of whether states choose to use the NADAC or another pricing methodology as a basis for payment, they will need to submit a state plan amendment in accordance with the state plan requirements</p>
90. NADAC	CMS should allow manufacturers to identify low volume drugs to be excluded from the survey.	<p>All drugs, including low volume drugs, that have sufficient reporting will be included in the survey as there is a benefit to obtaining acquisition cost information. Please review the NADAC methodology document that supplies this information in detail at:</p> <p>http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NADACdraftMethodology.pdf</p>
91. NADAC	Will states be penalized for exceeding NADAC payment amounts?	All state reimbursement policies are reviewed by CMS. Each state will be held accountable in light of their approved state plans, regardless of the payment methodology they choose as to how they reimburse for covered outpatient drugs. The NADAC files are designed to provide information regarding drug prices. Issues concerning state payment will be addressed in other documents.

Topic Category	Comment/Question	Response
92. NADAC	Increasing dispensing fees as a response to lowering drug ingredient reimbursement would be contrary to years of legal precedent. The national trend is to reduce dispensing fees, not increase them.	CMS expects that states calculate reasonable dispensing fees and ingredient costs, consistent with the statute, regulations, and applicable state plan.
93. NADAC	When will 'Draft' be removed from the files?	The NADACs are now finalized.
94. NADAC	When will states be able to begin using the NADAC in their reimbursement methodology?	<p>The NADAC files are designed to provide information regarding drug prices for state review.</p> <p>If a state chooses to use the NADAC or a different pricing methodology as a basis for payment, it will need to submit a state plan amendment in accordance with the state plan</p>